Supreme Court, U.S.
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No. 95-788

In The

Supreme Court of the United States

October Term, 1995

MARY DOE, preborn child in being as a human embryo, on behalf of herself and all others similarly situated, *et al.*,

Petitioners,

vs.

DONNA SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,

Respondents.

Petition for Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Does Mary Doe, a living human embryo *ex utero* and *in vitro* ("test tube baby"), upon the appointment of an appropriate guardian *ad litem* under Fed. R. Civ. P. 17(c), have both the capacity and standing to sue in federal court to enjoin the Government from making any use of a federal advisory committee's report recommending that the Government fund a wide range of research on live human embryos, killing these test tube babies, for violation of the requirement of the Federal Advisory Committee Act, 5 U.S.C. app. 2, § 5(b)(2), that such an advisory committee be "fairly balanced"?

2. Is the question whether a federal advisory committee is "fairly balanced" within the meaning of the Federal Advisory Committee Act, 5 U.S.C. app. 2, § 5(b)(2), a justiciable issue?

3. Did the Fourth Circuit err as a matter of law in holding that this matter became moot once the federal advisory committee had issued its report and recommendations and disbanded, and the Government had given some consideration to such report and recommendations, where the Government remains free in the future to continue to consider and rely on the committee's report and recommendations as support or justification for any decision to fund experimentation on live human embryos?

LIST OF PARTIES

Aside from Mary Doe, the other Petitioners are International Foundation for Genetic Research (The Michael Fund), a Pennsylvania nonprofit corporation, and Michael Policastro, by his next friend Patricia Policastro. Aside from Donna E. Shalala, Secretary of Health and Human Services, the other Respondents are the Department of Health and Human Services; Dr. Harold Varmus, in his official capacity as Director of the National Institutes of Health; the National Institutes of Health; Steven Muller, in his official capacity as member and Chairman of the NIH Human Embryo Research Panel; R. Alta Charo, Dr. Patricia K. Donahue, Dr. Kenneth J. Ryan, Thomas H. Murray, Dorothy Nelkin, Nannerl O. Keohane, Dr. Bernard Lo, Brigid L. M. Hogan, Dr. Mark R. Hughes, Ronald M. Green, Dr. Fernando Guerra, Andrew Hendrickx, Diane D. Aronson, Ola M. Huntley, Carol A. Tauer, Dr. Mary C. Martin, John J. Eppig, and Patricia A. King, in their official capacities as members of the NIH Human Embryo Research Panel; and the NIH Human Embryo Research Panel.

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The opinion of the United States District Court for the District of Maryland was issued on September 26, 1994, and is set forth in the Appendix at 9a. It has also been unofficially reported. *See Doe v. Shalala,* 862 F. Supp. 1421 (D. Md. 1994). The opinion of the Fourth Circuit Court of Appeals was issued on June 16, 1995, and is set forth in the Appendix at 3a. While an "unpublished disposition" has been reported, *see International Foundation for Genetic Research v. Shalala,* 57 F.3d 1066 (4th Cir. 1995), the Fourth Circuit's opinion has not been reported.

STATEMENT OF JURISDICTION

The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1). In an opinion issued June 16, 1995, the Fourth Circuit Court of Appeals found that the case had become moot while on appeal, vacated the judgment and order of the district court, and remanded with instructions that the case be dismissed. The final disposition of this case was the Fourth Circuit's Order denying Petitioners' Petition for Rehearing, issued on August 18, 1995 (1a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III of the Constitution of the United States provides in pertinent part as follows:

> The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority,—to all Cases affecting Ambassadors, other public Ministers and

> Consuls — to all Cases of admiralty and maritime Jurisdiction; — to Controversies to which the United States shall be a Party; — to Controversies between two or more States; — between a State and Citizens of another State; —between citizens of different States, — between citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

U.S. Const. art. III, § 2, cl. 1.

Section 10(a) of the Administrative Procedure Act provides as follows:

> § 701. Application; definitions
>
> (a) This chapter [5 USCS §§ 701 et seq.] applies, according to the provisions thereof, except to the extent that —
>
> (1) statutes preclude judicial review; or
>
> (2) agency action is committed to agency discretion by law.

5 U.S.C. § 701(a).

Section 3 of the Federal Advisory Committee Act provides as follows:

> § 3. Definitions
>
> For the purpose of this Act——
>
> (1) The term "Director"

[Administrator"] means the Director of the Office of Management and Budget [Administrator of General Services].

(2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is —

(A) established by statute or reorganization plan, or

(B) established or utilized by the President, or

(C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government except that such term excludes (i) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government.

> (3) The term "agency" has the same meaning as in section 551(1) of title 5, United States Code [5 USCS § 551(1)].
>
> (4) The term "Presidential advisory committee" means an advisory committee which advises the President.

5 U.S.C. app. 2, § 3.

Section 5 of the Federal Advisory Committee Act provides as follows:

> § 5. Responsibilities of Congressional committees; review; guidelines
>
> (a) In the exercise of its legislative review function, each standing committee of the Senate and the House of Representatives shall make a continuing review of the activities of each advisory committee under its jurisdiction to determine whether such advisory committee should be abolished or merged with any other advisory committee, whether the responsibilities of such advisory committee should be revised, and whether such advisory committee performs a necessary function not already being performed. Each such standing committee shall take appropriate action to obtain the enactment of legislation necessary to carry out the purpose of this subsection.

(b) In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall —

(1) contain a clearly defined purpose for the advisory committee;

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

(4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any),

> the duration of the advisory committee, and the publication of reports and other materials, to the extent that the standing committee determines the provisions of section 10 of this Act to be inadequate; and
>
> (5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.
>
> (c) To the extent they are applicable, the guidelines set out in subsection (b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee.

5 U.S.C. app. 2, § 5.

Rule 17(c) of the Federal Rules of Civil Procedure provides as follows:

> (c) Infants or Incompetent Persons. Whenever an infant or incompetent person has a representative, such as a general guardian, committee, conservator, or other like fiduciary, the representative may sue or defend on behalf of the infant or incompetent person. An infant or incompetent person who does not have a duly appointed representative may sue by a next friend or by a guardian ad

> litem. The court shall appoint a guardian ad litem for an infant or incompetent person not otherwise represented in an action or shall make such other order as it deems proper for the protection of the infant or incompetent person.

Fed. R. Civ. P. 17(c).

STATEMENT OF THE CASE

Mary Doe, a living human embryo *ex utero* and *in vitro* (commonly known as a "test tube baby"), and more than 20,000 others like her, face a real and imminent threat of being killed unless the Government is stopped from relying on the report and recommendations of a federal advisory committee as justification to approve pending applications for federal funding of human embryo experimentation. This Petition asks, in essence, that Mary Doe be given her day in court to show that the federal advisory committee's members were hand-picked by the Government to be financially predisposed and otherwise biased in favor of recommending the federal funding of human embryo experimentation, in gross violation of federal statutory requirements.

Petitioner Mary Doe is an unnamed baby girl who is a preborn child in being as a human embryo, and is one of more than 20,000 such embryos *ex utero* located in various *in vitro* laboratories in the United States (Amended Complaint, ¶¶ 4, 5). Petitioner International Foundation for Genetic Research (hereinafter "The Michael Fund"), is a nonprofit organization whose primary purpose is to sponsor research involving the genetic disorder known as Down's syndrome and similar inborn chromosomal disorders (*id.* ¶ 9, 45a). Petitioner Michael Policastro, after whom The Michael Fund is named, is 26 years

old and suffers from Down's syndrome (Amended Complaint, ¶8).[1]

Following passage of the NIH Revitalization Act of 1993, Pub. L. No. 103-43 (codified at 42 U.S.C. §§ 281 *et seq.*), Respondent National Institutes of Health (NIH) received a number of applications seeking federal financial support for research involving human embryos (Amended Complaint, ¶ 22, 42a, 78a-79a). As a result, during the fall of 1993, the Secretary of Health and Human Services, Respondent Donna Shalala, decided to create and appoint an advisory panel, known as the NIH Human Embryo Research Panel (hereinafter "the Panel") (Amended Complaint, ¶ 30, 31a, 79a). The Panel was charged by the Government with addressing the moral and ethical issues raised by the use of human embryos in research and with developing guidelines as to which areas of research involving human embryos would be acceptable for funding, which would require additional review, and which would be unacceptable for federal support (Amended Complaint, ¶ 31, 79a-80a, 83a).

After the Panel had commenced its work but before it issued its Report, Petitioners brought the instant action against the Government, alleging, inter alia, that the Panel, as created and appointed, violated the "fair balance" requirement of the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2, § 5(b)(2) (Amended Complaint, ¶¶ 41-42). Jurisdiction was based on the federal question statute, 28 U.S.C. § 1331 (*id.* ¶ 2). Petitioners

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1. During the pendency of this litigation, it was reported that the Jones Institute for Reproductive Medicine in Norfolk Virginia, began screening human embryos for Down's Syndrome *before* implanting them in the womb "Doctors Begin to Screen Embryos in Down's Trial," Chicago Tribune, 3/12/95. It likewise has been reported that St. Barnabas Medical Center in Livingston has begun screening for Down's Syndrome prior to implantation in the womb in their in vitro program. (The Star-Ledger, August 10, 1995.) We have become poor scientists and poor doctors if we kill a patient because we cannot cure their disease. In the case of Down's Syndrome, there is one chromosome too many, not an insufficiency of chromosomes.

alleged and, in response to the Government's Motion for Summary Judgment, provided evidentiary support, that at least 10 of the 19 members of the Panel were current or former NIH grantees who had firmly endorsed the principle and many of the protocols of extended and unfettered human embryo research (id., ¶ 32, 45a-77a). The Panel was thus predisposed to (and did) make recommendations in favor of the federal funding of research on living human embryos.

After holding a hearing on Petitioners' Motion for Preliminary Injunction and the Government's Motion for Summary Judgment, the district court, the Honorable Peter J. Messitte presiding, issued an Opinion on September 26, 1994 (9a), concluding that none of the Petitioners, including Petitioner Mary Doe, had the requisite standing to maintain this action in federal court (10a, 16a-24a). In addition, the district court concluded that the pivotal issue of the case, namely whether the Panel was established by NIH in violation of FACA's fair balance requirement, *see* 5 U.S.C. app. 2, § 5(b)(2), was not justiciable (10a, 24a-28a). Accordingly, the district court entered an Order dated September 26, 1994, denying Petitioners' Motion for Appointment of a Guardian *Ad Litem*, denying Petitioners' Motion for Preliminary Injunction, granting the Government's Motion for Summary Judgment, and dismissing Petitioners' Complaint and Amended Complaint (29a).

The day after the district court handed down its Opinion and Order, namely on September 27, 1994, the Panel issued its Report (122a).[2]

The Report set forth recommendations and guidelines that would allow the Government to fund a wide range of human embryo research, including both research on living embryos,

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2. A full copy of the Panel's Report will be submitted to the Court as a Lodging Appendix upon filing of the Petition for Writ of Certiorari.

such as Mary Doe, and the creation (fertilization/conception) of human embryos purely for research purposes (Lodging Appendix O, pp. ix-xx).

On December 2, 1994, the standing NIH Advisory Committee held a public hearing on the Report's recommendations and, as expected, voted to adopt the Panel's Report and recommendations in toto (90a-101a). They simply rubber-stamped it, underscoring the fact that this handpicked human embryo research panel was the true "advisory committee." Following the standing committee's action on the Report, on December 2, 1994, President Clinton issued a Statement that he had directed NIH not to allocate any federal funds for any research involving the creation (fertilization and conception) of human embryos for research purposes (102a). President Clinton's action, however, was a distinction without a difference because it did not in any way affect NIH's ability to proceed with federal funding of research on the more than 20,000 living embryos (test tube babies) "stored in the in vitro labs of the Nation", including Mary Doe (38a-41a).[3]

Additionally, the President's action does not preclude the sale of human embryos labeled "spare" embryos by in vitro labs to NIH grant recipients who will purchase them with federal dollars.

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3. In a letter dated April 7, 1995 and addressed to Senator Rick Santorum (R. Pa.), NIH's Acting Deputy Director for Science Policy and Technology Transfer, Sandy Chamblee, states that the President's "directive does not apply to research that involves an embryo already fertilized for a treatment purpose that is subsequently donated by a couple for study in research" (103a).

Interestingly the "treatment purpose" referred to here is simply the treatment of infertility by virtue of a woman's spouse participating in in vitro fertilization with her, during which procedure an average of eleven human embryos are conceived in vitro which are then implanted two at a time until pregnancy is achieved, with the "spares" left over then frozen in time in a state of cryopreservation.

On appeal, the Fourth Circuit Court of Appeals did not reach or decide the issues of standing and justiciability. Rather, in its Opinion issued on June 16, 1995, the appeals court found that the issuance of any injunctive relief to prevent further Government use of the Panel's Report "would be a futile gesture on our part, given that the Panel's report and recommendations have already been considered by NIH and indeed by the President" (7a-8a). The court, therefore, concluded that "[b]ecause we would not be able to provide the relief requested by appellants, even if we were to rule in their favor, we dismiss the appeal as moot" (8a). Accordingly, the Fourth Circuit, having found the case had become moot "while on appeal," vacated the judgment and order of the district court, and remanded with instructions that the action be dismissed (8a).

REASONS FOR GRANTING THE WRIT

I.

MARY DOE, A PREBORN HUMAN EMBRYO *IN VITRO*, MAY SUE IN FEDERAL COURT UPON APPOINTMENT OF AN APPROPRIATE GUARDIAN *AD LITEM*, AND HAS STANDING TO ASSERT THAT THE NIH ADVISORY PANEL WAS COMPOSED IN VIOLATION OF FACA.

This Petition presents a novel and fundamental issue of federal law, namely whether a living human embryo *in vitro* (test tube baby), to avoid being killed, has both the capacity and standing to sue in federal court to enjoin the Government from relying on a report issued by a biased and grossly unbalanced advisory panel approving research upon the human embryo and vivesection and destruction of these test tube babies with federal monies.

Fed. R. Civ. P. 17(c) mandates that a court "shall appoint a

guardian ad litem for an infant or incompetent person not otherwise represented in an action[.]" Indeed, the district court correctly recognized that, assuming "a human embryo has independent legal interests capable of protection, it is clear that any such interests would have to be protected through the person of a *guardian ad litem*" (16a). *Doe v. Shalala*, 862 F. Supp. at 1421, 1426 (D. Md. 1994) (citing Fed. R. Civ. P. 17(c)).

In nevertheless determining that the suit "cannot proceed as to 'Mary Doe'" (16a-17a), *Doe v. Shalala, supra*, 862 F. Supp. at 1426, the district court relied heavily on this Court's holding in *Roe v. Wade*, 410 U.S. 113, 158 (1973), that the word "person," as used in the fourteenth amendment, does not include human fetuses. By analogy of reasoning, it concluded that "embryos are not persons with legally protectable interests within the meaning of Fed. R. Civ. P. 17(c) such that appointments of guardians *ad litem* are warranted or required" (17a). *Doe v. Shalala, supra*, 862 F. Supp. at 1426. It saw "no distinction between fetuses *in utero* or *ex utero*" (17a). *Id.*

Petitioners submit that the district court erroneously failed to recognize that "the scope of [Rule 17(c)] has been extended to permit a court to appoint a guardian *ad litem to represent the interests of unborn children.*" 6A C. Wright, A. Miller & M. Kane, *Federal Practice & Procedure* § 1570 at 504 (1990) (emphasis added). While most federal cases decided to date have involved the appointment of a guardian *ad litem* to protect the financial interests of an unborn child,[4] the rationale of these

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4. *See Hatch v. Riggs National Bank*, 361 F.2d 559 (D.C. Cir. 1966) (suggesting that a guardian *ad litem* be appointed to represent the interests of unborn heirs), *on remand*, 284 F. Supp. 396 (D.D.C. 1968) (appointing guardian *ad litem* to protect interests of unborn heirs); *In re Joint Eastern & Southern District Asbestos Litigation*, 129 B.R. 710, 772 (E.D.N.Y. & S.D.N.Y. 1991) (recognizing that "[w]hen faced with a modification of a trust, courts have appointed legal representatives for unborn . . . trust beneficiaries"

(Cont'd)

decisions points inexorably to the conclusion that a guardian *ad litem* should also be appointed to protect the interests of an unborn person in shielding his or herself from death, disease, or physical injury.[5] Like a child or incompetent person, unborn children in the form of human embryos *in vitro*, whose very existence would be threatened by federally funded medical research, are "not in a position to protect their own interests." *In re Joint Eastern & Southern District Asbestos Litigation*, 129 B.R. 710, 773 (E.D.N.Y. & S.D.N.Y. 1991), *vacated on other grounds*, 982 F.2d 721 (2d Cir. 1992).

Moreover, this Court's holding in *Roe v. Wade, supra*, that a fetus is not a "person" for purposes of the fourteenth amendment, "does not mandate the conclusion that the fetus [or the human embryo] is a legal nonentity." *O'Grady v. Brown*, 654 S.W.2d 904, 910 (Mo. 1983) (term "person" as used in state wrongful death statute includes fetus *in utero*). *Roe v. Wade, supra*, involved the issue of abortion, an issue necessitating the resolution of the mother's rights as against her unborn child when the two are in conflict. *O'Grady v. Brown, supra*, 654 S.W.2d at 910. The instant case, by contrast, does not involve abortion, nor does it pit the interests of the human embryo, Mary Doe, against that of her natural mother. Mary Doe's interests in her physical

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(Cont'd)

and that "[t]his equitable power has been invoked by other courts in class actions where members of the plaintiff class were . . . unborn"), *vacated on other grounds*, 982 F.2d 721 (2d Cir. 1992); *In re UNR Industries, Inc.*, 29 B.R. 741, 744 n.3 (N.D. Ill. 1983) ("The Court does not doubt its power to appoint a guardian *ad litem* to represent 'an infant or incompetent,' Fed. R. Civ. P. 17(c), or even *to represent unborn persons*" (emphasis added)) (citing *Hatch*), *appeal dismissed*, 725 F.2d 1111 (7th Cir. 1984).

5. *See Wainwright v. Moore*, 374 So. 2d 586, 588 (Fla. DCA 1979) (trial court erred in refusing to appoint a guardian *ad litem* for the unborn child of a prisoner, an expectant mother, who sought injunctive relief to allow her to keep her newborn child with her in prison for the first 18 months of the child's life).

integrity and continued existence are threatened not by her mother, but by a third party, the Government, which plans to fund research that would kill her. The Government has no constitutional right to kill an unborn fetus or embryo, either *in utero* or *ex utero*.[6]

Aside from being entitled to the appointment of a guardian *ad litem*, Mary Doe has demonstrated standing for purposes of the Article III "case or controversy" requirement, by showing that she "'personally has suffered some actual or *threatened* injury as a result of the putatively illegal conduct of the defendant.'" *Heckler v. Mathews*, 465 U.S. 728, 738 (1984) (quoting *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99 (1979) (emphasis added)). The challenged actions of the Government threaten to result in approval for federal funding of experimentation upon live human embryos, resulting in their death.

Moreover, this threatened injury "fairly can be traced to the challenged action of the defendant." *Simon v. Eastern Welfare Rights Organization*, 426 U.S. 26, 41 (1976).

Finally, Mary Doe's interest in this litigation is "'likely to be redressed by the requested relief.'" *International Primate Protection League v. Administrators of Tulane Educational Fund*, 500 U.S. 72, 77 (1991) (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)). By enjoining any further use by the

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6. Nor does *Roe v. Casey*, 464 F. Supp. 483, 486-87 (E.D. Pa. 1978), *aff'd*, 623 F.2d 829 (3d Cir. 1980), provide support for the district court's decision. The court in *Casey* refused to appoint guardians *ad litem* to protect the unborn because such unborn persons had no "legally protectable interest" vis-a-vis the plaintiffs, pregnant women, in view of this Court's decision in *Roe v. Wade, supra*. This case, however, does not involve the issue of abortion or the constitutional rights of the mother, since all of the more than 20,000 embryos in question, including Mary Doe, are *ex utero* and *in vitro*.

Government of the Panel's Report or recommendations, the threat of injury to the physical integrity and viability of Mary Doe and other human embryos *in vitro* will be significantly reduced. Moreover, forcing the Government to meet the FACA requirement that "the [Panel] be fairly balanced in terms of the point of view represented," 5 U.S.C. app. 2, § 5(b)(2), would likely result in appointment of a new advisory committee or panel (hopefully containing at least one human embryologist as the instant panel curiously did not) that would take a far harder look at funding experiments on live human embryos.

While the Government could conceivably go forward with federal funding of human embryo experimentation even without the Panel's Report and recommendations (23a), *Doe v. Shalala, supra,* 862 F. Supp. at 1429, that Report is unquestionably "potentially influential to the outcome" of this extremely serious and very controversial policy question. *Alabama-Tombigbee Rivers Coalition v. Department of Interior,* 26 F.3d 1103, 1106 (11th Cir. 1994). It is far less likely that the Government will ultimately decide to fund human embryo research if it is barred from using the Report as support and justification for undertaking such a controversial policy. Human embryo experimentation remains illegal in ten major nations of the world (106a-107a). The laws of these nations require those conducting experiments to absolutely respect these marvelously young human beings and treat any exploitation of the early human embryo as intrinsically repugnant.

Mary Doe represents human life in its most nascent or elemental form. The messaging material of the new life is entirely complete and present with nothing remaining to be added, reduced to the smallest subscript of the universe. Every citizen of the United States began his or her life as a human embryo. To deny Mary Doe the capacity and standing to sue in federal court to protect her vital interests in preserving her existence and physical

integrity against a Government bent on funding the invasion and destruction of her as a human being would be to deny not only the humanity of our origins but also the humaneness of our system of justice.

II.

FACA'S FAIR BALANCE REQUIREMENT IS JUSTICIABLE.

This Petition also presents an important question of federal law as to whether the key issue of this lawsuit, namely whether the Panel was "fairly balanced" within the meaning of FACA, *see* 5 U.S.C. app. 2, § 5(b)(2), is justiciable. Congress did not express an intention to preclude judicial review of appointments made to advisory committees under FACA's "fair balance" requirement. Thus, the only conceivable basis for the district court's holding is a determination that Petitioners' suit is barred by § 10(a)(2) of the Administrative Procedure Act (APA) because the agency action at issue "is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). This holding cannot be sustained since the Government has failed to establish that the fair balance requirement "is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

The evidence in this case would have shown, had the matter not been summarily dismissed by the courts below, that the Government would have been hard put to appoint a panel less inclined to perform an intensive review of the "profound ethical and moral questions" (102a) surrounding the proposed federal funding of human embryo research. Of the Panel's 19 members, at least 10 were current or former NIH grantees[7] who had firmly

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7. For example, Dr. Kenneth J. Ryan, a specialist in late-term eugenic abortions by prostaglandin induction, received grants in excess of $3,997,500 (Cont'd)

endorsed the principle, as well as many of the protocols, of extended and unfettered research and experimentation on live human embryos (45a-77a). Thus, a majority of Panel's members were not only categorically predisposed to favor experimentation on human life, but were also in a position to profit financially from the promotion of the very activities most likely to harm Mary Doe.[8]

It was to prevent this very abuse of "government by insiders," that Congress enacted FACA's fair balance requirement.[9] Indeed, this Court has recognized that "FACA was enacted to cure specific ills, *above all the wasteful expenditure of public funds for . . . biased proposals*[.]" *Public Citizen v. Department of Justice*, 491 U.S. 440, 453 (1989) (emphasis added). That the "fair balance" requirement was designed to help prevent the domination of federal advisory committees by special interest groups can be seen from the House Report, which warned that "[o]ne of the greatest dangers in the unregulated use of advisory committees is that special interest groups may use their membership on such bodies to promote their private concerns." H.R. Rep. No. 1017, 92d Cong., 2d Sess. 6 (1972), *reprinted in* 1972 U.S. Code Cong. & Admin. News 3491, 3492.

(Cont'd)
between 1987 and 1992 (55a-56a). Panel members Eppig, Nelkin, Hogan, Murray, Hughes, Donahoe, Guerra, Hendrickx, Martin, and Lo have also received NIH grants in recent years (*see* 57a-77a).

8. Moreover, the remaining members of the Panel were of a like mind with their fellows, as demonstrated by their expression, during the Panel's discussions, of strong support for experimentation on human embryos without ethical restraint (35a-37a).

9. FACA also requires that measures be taken to "ensure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority *or by any special interest*, but will instead be the result of the advisory committee's independent judgment." 5 U.S.C. app. 2, § 5(b)(3) (emphasis added).

By holding that any violation of FACA's fair balance requirement is nonjusticiable, the district court improperly reduced Congress's command to a toothless advisory directive. It agreed with *Public Citizen v. Department of Health & Human Services*, 795 F. Supp. 1212 (D.D.C. 1992), which in turn followed the reasoning of Judge Silberman's concurring opinion in *Public Citizen v. National Advisory Committee on Microbiological Criteria for Foods*, 886 F.2d 419, 426 (D.C. Cir. 1989) (Silberman, J., concurring in the judgment). But, as Chief Judge Edwards correctly observed in his separate opinion in *Microbiological*:

> While the difficulty of determining what precisely constitutes a "fair balance" may incline courts to be deferential in reviewing the composition of advisory committees and may defeat a plaintiff's claim in a given case, this cannot be grounds for refusing to enforce the provision altogether. . . . Judicial responsibility cannot be abdicated merely because a case poses a difficult question for resolution.

Id. at 434 (Edwards, C.J., concurring in part and dissenting in part). Indeed, most federal courts have found that the question of whether a panel is fairly balanced is not so difficult as to defy judicial analysis, and have generally looked to the purpose of the advisory committee in question in determining whether the requirement has been met.[10]

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10. *See Public Citizen v. National Advisory Committee on Microbiological Criteria for Foods*, 708 F. Supp. 359, 362, 363 (D.D.C. 1988) (court looked to whether committee was able to "perform its limited function fairly and impartially"; where advisory committee was convened essentially for technical expertise in selection of foods, reliance on members with extensive scientific backgrounds, many of whom worked in positions in food

(Cont'd)

The purpose of the Panel was not merely to determine protocols for the conduct of human embryo experimentation. Rather, the Panel was charged with making a *profound, threshold determination as to whether any federal funding of human embryo experimentation was moral and ethical.*

Given its composition, the Panel could not make an unbiased decision on this issue of such immense consequence to the lives of thousands of human embryos and fairly reflect and hold forth to the world the moral stance of the United States of America on this grave and epoch making issue.

The Panel was deliberately "stacked" with members who not only were of one mind or viewpoint with respect to whether the federal government should fund human embryo research, but who stood to benefit directly and financially from conducting what many in the nation consider morally and ethically objectionable experimentation on live human embryos. Thus, the FACA fair balance requirement was clearly violated.

It must be emphasized that Petitioners do not assert that FACA's fair balance requirement has been violated simply because balanced viewpoints were not represented on the Panel. Rather, Petitioners have also undertaken to show that the Panel was deliberately packed by NIH with members of the industry or institutions who would benefit financially from conducting experiments on human embryos. To adjudicate Petitioners' fair balance claim will therefore not require the federal courts to "arbitrarily substitute [their] judgment for that of the agency,"

(Cont'd)
industry, was proper in view of committee's functions); *see also National Anti-Hunger Coalition v. Executive Committee of President's Private Sector Survey on Cost Control,* 711 F.2d 1071, 1074 (D.C. Cir. 1983) (committee staffed by executives of large private organizations was appropriately balanced in view of the committee's assignment to apply private sector experience to attain cost-effective management in federal government).

Public Citizen v. Department of Health & Human Services, supra, 795 F. Supp. at 1220-21, as to which points of view should be represented on the Panel. A reviewing court need only determine whether NIH abused its discretion by appointing to the Panel a majority of members having vested financial interest in advocating a single point of view, namely that of promoting federal funding of human embryo research.

In short, this is not a case in which the applicable statutory standard "fairly exudes deference" to the agency and thus "foreclose[s] the application of any meaningful judicial standard of review." *Webster v. Doe,* 486 U.S. 592, 600 (1988). The Court should grant the Petition to prevent the Government from hiding beneath the cloak of nonjusticiability while partaking of the poisoned fruit of a Panel that served as "a convenient nesting place for special interest groups seeking to change . . . federal policy for their own ends." 118 Cong. Rec. 30,276 (1972) (Senate staff report submitted for the record by Senator Percy).

III.

BECAUSE THE GOVERNMENT REMAINS FREE TO USE THE PANEL'S REPORT TO JUSTIFY ANY DECISION TO FUND HUMAN EMBRYO RESEARCH, THIS CASE IS NOT MOOT.

The fact that the Panel's Report is still extant and being circulated, and that the Government is free to rely on the Report's recommendations and guidelines in making funding decisions, means that this case is still a live controversy and is not moot. A case or controversy continues to exist where "the challenged government activity . . . is not contingent, has not evaporated or disappeared, and, by its continuing and brooding presence, casts what may well be a substantial ADVERSE effect on the interests of the petitioning parties." *Super Tire Engineering Co. v.*

McCorkle, 416 U.S. 115, 122 (1974). The Panel's Report, poisoned by the FACA violation, continues to have adverse consequences on Petitioners' interests, since Government funding decisions remain to be made, this year and in future years, and the prejudicial Panel's Report can be relied upon in making those decisions.[11]

Although the Report has already been disclosed and considered to some extent by NIH and the President, a declaration that it was issued in violation of FACA, together with appropriate injunctive relief, would certainly preclude Government decisionmakers from citing or using it in the future to justify the funding of human embryo research. Such declaratory and injunctive relief could lead to new, unbiased studies that would more fairly address the FUNDAMENTAL MORAL and ETHICAL issues surrounding human embryo experimentation. The mere fact that the Report has already received some consideration by the Government does not mean that a court could not grant *any* relief which would preclude any further consideration or use of the Report. *Cf. In re Grand Jury Investigation No. 78-184*, 642 F.2d 1184, 1187-88 (9th Cir. 1981) (disclosure of many grand jury materials did not render action to retain secrecy of materials moot since further disclosure could be prevented and limits could be placed on personnel who may have access), *aff'd sub nom. United States v. Sells*, 463 U.S. 418 (1983); *Cell Associates, Inc. v. National Institutes of Health*, 579 F.2d 1155 (9th Cir. 1978) (action to prevent NIH from disclosing

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11. That NIH's review of the Panel's Report did not end on December 2, 1994, with the adoption of the Report by the NIH Advisory Committee and the issuance of President Clinton's Statement, can be seen from an April 7, 1995 letter addressed to Senator Rick Santorum (R. Pa.), wherein NIH's Acting Deputy Director for Science Policy and Technology, Sandy Chamblee, states that "[a]t this juncture, the NIH *is still reviewing* the report of a panel that met last year to study the ethical, medical, scientific, and public policy implications of Federal funding of research involving human in vitro fertilization and the preimplantation embryo (test tube baby)" (103a (emphasis added)).

an investigative report was not moot, even though the report had been published by the media; willingness of NIH to permit anyone to see and obtain copies of report continued to harm plaintiff).

As a practical matter, the current Administration cannot afford to take such a controversial step as using taxpayer funds to finance experiments on live human embryos without being able to point to this Panel's Report, to justify its decision. Thus, if Government use of the Report is enjoined, it will be forced to go back to square one and start all over again.[12]

Thus, since issuance of an injunction in this case would neither be "pointless" nor a "futile gesture" (7a), the Court should grant the Petition, reverse the Fourth Circuit's erroneous mootness determination, and give Mary Doe her day in court on the fundamental legal issues of this case, since otherwise her very

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12. Even assuming that mootness were a close question in this case, this controversy falls within an exception to the mootness doctrine because it is "capable of repetition yet evading review." *Weinstein v. Bradford*, 423 U.S. 147, 148-49 (1975) (citing *Southern Pacific Terminal Co. v. ICC*, 219 U.S. 498 (1911)). Given the limited purposes for which federal advisory panels are assembled under FACA, this case is a classic example of the kind of action that is too short in duration to be fully litigated. Moreover, Petitioners are likely to be aggrieved by similar actions undertaken by the Government in the future, particularly in light of the professed intention of President Clinton to establish other panels to investigate and report on embryo research (102a). *See Arkansas AFL-CIO v. Federal Communications Commission*, 11 F.3d 1430, 1435 (8th Cir. 1993) (case challenging agency decision on the application of the fairness doctrine fell within mootness exception even though election at issue had already occurred, since there was a continuing debate over the issue involved in the election and the parties could be expected to be involved in a similar dispute); *Sinai Hospital of Baltimore, Inc. v. Scearce*, 561 F.2d 547, 551-52 (4th Cir. 1977) (issues surrounding appointment of board of inquiry to investigate labor dispute fell within mootness exception given the short time period such disputes normally last).

right to be, and continue to exist as a marvelously small human being (test tube baby) shall be taken away by this sole, insidiously stacked panel.

CONCLUSION

Mary Doe, as a marvelously young human being, should not have to prove her inviolability.

NIH AND THIS ADMINISTRATION SHOULD HAVE TO PROVE BY WHOSE AUTHORITY DO THEY PROPOSE TO SET ASIDE HER INVIOLABILITY AS OF NO CONSEQUENCE IN ORDER THAT THEY MAY EXPERIMENT UPON HER AND VIVISECT HER AND DESTROY HER.

The equal humanity of the human embryo has been brought to the doorstep of this Court by the new science of *in vitro* fertilization (test tube babies).

Mary Doe, as a test tube baby, is a being; and being human, she is a human being.

If the test tube were to say: "This is my property" no one would believe the test tube.

She is "person" and not "property" because she is the only property which has the property of building herself.

She is fully differentiated from fertilization (conception) and will build herself as a little "astronaut in utero" upon implantation in the womb.

She demonstrates her incredible viability by being stored for years in the deep freeze of cryopreservation, and upon being

thawed and implanted in the "temple of the womb" becomes no longer a "test tube baby" but the baby we refer to as "Mary" or "Peter."

NIH and the current administration propose to experiment upon and vivisect Mary Doe and the tens of thousands of test tube babies like her, stored throughout the Nation's *in vitro* labs. The government terms these test tube babies, "abandoned human embryos." As such, they are "orphaned" to the test tube, stored by the thousands in the deep freeze of cryopreservation. They are the sisters and brothers of the babies conceived by the technique of *in vitro* fertilization, waiting to be rescued from the deep freeze of the concentration can by their mother who has left them behind after giving birth to their sister or brother.

They could be readily adopted by the many childless couples in the Nation by being implanted in the womb of an adopting mother.

One such childless couple made just that request of NIH (they asked to adopt one of the twenty thousand "abandoned" test tube babies that will otherwise be vivisected in experimentation). They made this request through their Senator Rick Santorum's office and received the following reply letter from NIH to Senator Santorum (103a).

Mary Doe is entitled to the appointment of a guardian ad litem to protect her interests.

Medical science, speaking through the world dean of geneticists, the late Dr. Jerome Lejeune, of Paris, France (transcription of lecture delivered at Providence Hospital, October, 1993, a 32-minute portion of which was replayed by video tape in the District Court below, 108a) summarized the scientific facts thusly:

> THE BEGINNING OF OUR PERSONAL LIFE HAS TO ARISE AT THE MOMENT OF CONCEPTION AND AT THE LATEST TIME AT THE SPLITTING IN THREE CELLS. THEN WHEN PEOPLE ARE DISCUSSING WHEN DOES OCCUR THE INDIVIDUAL, WHEN DOES OCCUR THE UNITY AND THE UNICITY WE CAN ANSWER — WE KNOW, IT OCCURS AT CONCEPTION AND IF THERE ARE SOME MISTAKE MAYBE A FEW HOURS AFTER CONCEPTION BUT NO LATER THAN THAT.
>
> Well let us suppose that we agree because science tells us that, what is a human being. A HUMAN BEING IS A MEMBER OF OUR SPECIES. And then, if we are science, WHAT IS A PERSON? IT IS A HUMAN BEING ALIVE. And science HAS no other answer.

(120a).

What will this Court say, as the highest authority on the constitutional status in this nation of Mary Doe?

That is the very question presented to the wisdom of this body in our constitutional system of American jurisprudence. Is she entitled to the appointment of a guardian to protect her interests?

Aside from the constitutional question that this Court shall decide (even a denial of Mary Doe's Petition for Writ of Certiorari is a decision, because history cannot ignore the tens of

thousands of test tube babies that will be destroyed unless this Court acts) Mary Doe is inviolable as an early-on human being.

The decision of the Court in this case shall be epoch-making with ramifications into the 21st century.

Above and beyond United States constitutional law, the question of the equal humanity of Mary Doe deals with the universal prohibition against slavery or killing. The Court in the instant case, finds itself at the same juncture as the Court in the era of Dred Scott. Dred Scott, as a slave, was denied standing. Mary Doe, a bioslave seeks standing at the close of the twentieth century. If the work of this stacked panel is allowed to stand, history shall record this THE key turning point for it shall be the beginning of a new EPOCH of BIOSLAVERY in the United States — a slavery more heinous than the slavery of Babylonia, Assyria, Egypt, Persia and Colonial America combined

This new epoch is marked by the coining of new terms, words and phrases that were never in the human speech before that are used to depersonalize and dehumanize the human embryo by those desiring to enslave her, buy and sell her as property and arbitrarily kill her in order to experiment upon her, and create a new class of property: the bioslave. We see these new words and phrases replete in the bound copy of the NIH Human Embryo Research Panel report, attached as an appendix lodging to this Petition for Certiorari: "Pre-embryo;" "preimplantation embryo;" "*ex utero* preimplantation human embryo;" "chimera" (experimental combining of man and chimpanzee, NIH Report of the Human Embryo Research Panel, hereinafter Embryo Panel Report, p. 31, *see* Lodging Appendix); "spare embryo" (embryos left over from IVF fertilization in women).

A telling dissent of one panel member, Patricia King, expressed it thusly: "The fertilization of human oocytes [female

eggs] for research purposes is unnerving because human life is being created [conceived] solely for human *use*. I do not believe that this society has developed the conceptual frameworks necessary to guide us down this slope. My concerns are heightened in the context of research activities where practices cannot be monitored easily by the public and where it is difficult to ascertain whether the research is being conducted responsibly. (Embryo Panel Report, p. 97).

The Panel's report itself admits to the recategorization of human embryos as "*property*" for commercial purposes (Embryo Panel Report, p. 54): "Many people view the buying and selling of research embryos as devaluing human life by defining it as property and harming men and women by defining them as potential sources of research materials." ; "a market for eggs for IVF programs is now flourishing. Advertisements in student newspapers and medical school bulletin boards suggest that prices for eggs are already set by supply and demand." (Embryo Panel Report, p. 54); "Women and Girls Who Have Died are a source of ovaries to be harvested." (Embryo Panel Report, p. 59), "resulting in heretofore unheard of situations where a child's genetic mother was never born." (Embryo Panel Report, p. 60). The Panel itself recognizes the human embryo is "The child to be born." "This distinction in treatment between embryos that will be transferred (to a woman's uterus) and those that will not is warranted by the need to avoid harms to THE CHILD WHO COULD BE BORN." (Emphasis added) (Embryo Panel Report, p. xv). The Human Embryo Research Panel decided that an Ethics Advisory Board (EAB) was not needed: "The Panel does not recommend that an Ethics Advisory Board (EAB) be reconstituted for the purpose of reviewing research protocols involving embryos and fertilized eggs." (Embryo Panel Report, p. xvi).

The epochal implications of changing Imago Dei itself are

intimated by the panel: "A few chimeras between sheep and goats have been obtained. It is theoretically possible to make chimeras between human embryos and closely related primates, such as chimpanzees . . ." (Embryo Panel Report, p. 43).

By whose authority does this administration and all those advocating the agenda of reclassifying test tube babies as property do this? Who has said they may begin bioslavery in this nation which is not permitted in 10 major nations of the world where it remains a crime to experiment upon human embryos (106a-107a).

It is by the authority of their own hand-picked NIH "Human Embryo Research Panel" that they choose to do this — a stacked panel which not only illegally set policy for the nation, but decided grave moral questions for our people as well.

For all the foregoing reasons, Petitioners request that their Petition for Writ of Certiorari be granted.

Respectfully submitted,

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APPENDIX A — ORDER DENYING PETITION FOR REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT FILED AUGUST 18, 1995

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

FILED
August 18, 1995

No. 94-2367
CA-94-1703-PJM

INTERNATIONAL FOUNDATION FOR GENETIC RESEARCH (THE MICHAEL FUND), a Pennsylvania nonprofit corporation; MICHAEL POLICASTRO, by his next friend Patricia Policastro; MARY DOE, preborn child in being as a human embryo, on behalf of herself and all others similarly situated,

Plaintiffs-Appellants,

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, in her official capacity; DEPARTMENT OF HEALTH AND HUMAN SERVICES; HAROLD VARMUS, Dr. in his official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; STEVEN MULLER, in his official capacity as member and Chairman of the NIH Human Embryo Research Panel; R. ALTA CHARO, PATRICIA K. DONAHOE, Dr., KENNETH J. RYAN, Dr., THOMAS H. MURRAY, DOROTHY NELKIN, NANNERL O. KEOHANE, BERNARD LO, Dr., BRIGID L. M. HOGAN,

Appendix A

MARK R. HUGHES, Dr., RONALD M. GREEN, FERNANDO GUERRA, Dr., ANDREW HENDRICKX, DIANE D. ARONSON, OLA M. HUNTLEY, CAROL A. TAUER, MARY C. MARTIN, Dr., JOHN J. EPPIG, and PATRICIA A. KING, in their official capacities as members of the NIH Human Embryo Research Panel; NIH HUMAN EMBRYO RESEARCH PANEL,

Defendants-Appellees.

ORDER

Appellant has filed a petition for rehearing.

The Court denies the petition for rehearing.

For the Court,

/s/ Bert M. Montague
CLERK

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT DATED JUNE 16, 1995

UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 94-2367

INTERNATIONAL FOUNDATION FOR GENETIC RESEARCH (THE MICHAEL FUND), a Pennsylvania nonprofit corporation; MICHAEL POLICASTRO, by his next friend Patricia Policastro; MARY DOE, preborn child in being as a human embryo, on behalf of herself and all others similarly situated,

Plaintiffs-Appellants,

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, in her official capacity; DEPARTMENT OF HEALTH AND HUMAN SERVICES; HAROLD VARMUS, Dr., in his official capacity as Director of the National Institutes of Health, NATIONAL INSTITUTES OF HEALTH; STEVEN MULLER, in his official capacity as member and Chairman of the NIH Human Embryo Research Panel; R. ALTA CHARO, PATRICIA K. DONAHOE, Dr., KENNETH J. RYAN, Dr., THOMAS H. MURRAY, DOROTHY NELKIN, NANNERL O. KEOHANE, BERNARD LO, Dr., BRIGID L. M. HOGAN, MARK R. HUGHES, Dr., RONALD M. GREEN, FERNANDO GUERRA, Dr., ANDREW HENDRICKX, DIANE D. ARONSON, OLA M. HUNTLEY, CAROL A. TAUER, MARY C. MARTIN, Dr., JOHN J. EPPIG, and PATRICIA A. KING, in

their official capacities as members of the NIH Human Embryo Research Panel; NIH HUMAN EMBRYO RESEARCH PANEL,

Defendants-Appellees.

Appeal from the United States District Court
for the District of Maryland, at Greenbelt.
Peter J. Messitte, District Judge.
(CA-94-1703-PJM)

Argued: May 1, 1995

Decided: June 16, 1995

Before WIDENER, LUTTIG, and WILLIAMS,
Circuit Judges.

Vacated and remanded by unpublished per curiam opinion.

COUNSEL

ARGUED: Rudolph Martin Palmer, Jr., Hagerstown, Maryland, for Appellants. Jacob Matthew Lewis, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees.

ON BRIEF: Frank W. Hunger, Assistant Attorney General, Mark B. Stern, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees.

Unpublished opinions are not binding precedent in this circuit. See I.O.P. 36.5 and 36.6.

Appendix B

OPINION

PER CURIAM:

In late 1993, the Department of Health and Human Services (HHS) established a nineteen-member Human Embryo Research Panel (Panel) to serve as "a panel of special consultants" to the Advisory Committee to the Director of the National Institutes of Health (NIH), and to "recommend guidelines for Federal funding of human embryo research." J.A. at 66. Requests for such funding had been flowing into NIH since enactment of the NIH Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122 (codified at 42 U.S.C. § 289a-1), which removed various obstacles to the funding of research involving human embryos. More specifically, Panel members were asked "to consider various areas of research involving the human embryo and provide advice as to those areas they view to be acceptable for Federal funding, areas that warrant additional review, and areas that are unacceptable for Federal support." J.A. at 66. The Panel held five public meetings between February 1994 and June 1994 as it formulated its recommendations.

In June 1994, while the Panel was in the midst of its deliberations, the appellants — who are opposed to human embryo research for various reasons[1] — brought this action

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1. Mary Doe, "a preborn child in being as a human embryo," opposes research on human embryos for obvious reasons. The basis for the other appellants' opposition to embryonic research is less immediately apparent: Michael Policastro, who suffers from Down's Syndrome, and the International Foundation for Genetic Research ("The Michael Fund"), a Down's Syndrome research advocacy group, both fear that if the federal government were to expend funds on embryonic research, it would be forced to reduce the amount of funding it devotes to Down's Syndrome research. J.A. at 42-43. Policastro and the Michael Fund also fear that the (Cont'd)

seeking to prevent the Panel from proceeding further with its assignment. The appellants contended that the Panel violated the requirement of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, that "the membership of [an] advisory committee[2] . . . be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." *Id.* at 5(b)(2). Thus, they complained, the Panel, "as presently constituted, is predisposed to recommend that the Secretary not withhold federal funding from at least some human embryo research projects," because "at least 10 of the 19 members of said Panel are current or former NIH grantees who have endorsed the principle and many of the protocols of extended and unfettered human embryo research." J.A. at 45. Their complaint requested relief in the form of (1) a declaration that the Panel violates the FACA's "fair balance" requirement, (2) the dissolution of the Panel, (3) an injunction against future meetings of and action by the Panel, and (4) a declaration that all actions undertaken by the Panel are "null and void in their entirety." J.A. at 53-54.[3]

(Cont'd)
practice of human embryo research "will have the effect of making socially acceptable, and ultimately fully legal, the destruction of people affected with Down's syndrome." J.A. at 42.

2. The appellees vigorously contend that the Panel was not an "advisory committee" subject to the FACA requirements. Because we find this appeal to be moot, we do not address this or any other argument raised by the appellees.

3. The appellants also contended that § 101(b) of the NIH Revitalization Act of 1993, 42 U.S.C. § 289a-1(b), is unconstitutional, and sought a declaration to that effect, as well as an injunction preventing the future appointment of ethics advisory boards or panels pursuant to that Act. *See* J.A. at 53-54. However, it appears that the appellants have abandoned this claim, as it is not discussed in their briefs before this court; indeed, there is some question as to whether this claim was ever ripe, because the Panel may not have been appointed pursuant to that Act. To the extent that the
(Cont'd)

Appendix B

In August 1994, the appellants moved for a preliminary injunction "to prevent the Panel from holding any meetings or making any recommendations to NIH or the Secretary of Health and Human Services with regard to the issue of human fetal research." *Doe v. Shalala*, 862 F. Supp. 1421, 1423 (D. Md. 1994). The Secretary responded with a motion in opposition, as well as a motion for summary judgment as to the case as a whole. The district court denied the appellants' request for a preliminary injunction, and granted the Secretary's motion for summary judgment, holding that the appellants failed to meet several standing requirements, and that the alleged violation of the FACA's "fair balance" requirement was nonjusticiable. *See id.* at 1426-31. This appeal followed.

On September 27, 1994, one day after the district court dismissed this case, the Panel issued its report and recommendations. The Advisory Committee to the Director of NIH adopted that report and those recommendations on December 2, 1994; that same day, President Clinton issued a press release thanking the Panel for its efforts and commenting on its recommendations. J.A. at 210. Because the Panel has concluded its meetings, has issued its report and recommendations, and is apparently no longer in existence, an order dissolving the Panel, or enjoining it from holding further meetings or issuing its recommendations, would be pointless. Appellants urge that we could declare the Panel's actions "null and void in their entirety," and issue an injunction preventing NIH from considering the Panel's recommendations, but we believe that this, too, would be a futile gesture on our part, given

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(Cont'd)
claim was at some point ripe and that appellants have not abandoned their claim that § 101(b) is unconstitutional, the completion of the Panel's activities renders this claim no longer ripe for review.

that the Panel's report and recommendations have already been considered by NIH and indeed by the President.[4] Because we would not be able to provide the relief requested by appellants, even if we were to rule in their favor, we dismiss this appeal as moot. *See, e.g., Iron Arrow Honor Society v. Heckler,* 464 U.S. 67, 70 (1983) ("Federal courts lack jurisdiction to decide moot cases because their constitutional authority extends only to actual cases and controversies. To satisfy the Art. III case-or-controversy requirement, a litigant must have suffered some actual injury that can be redressed by a favorable judicial decision." (citation omitted)); *Conyers v. Reagan,* 765 F.2d 1124, 1127 (D.C. Cir. 985) ("[T]he actions that appellants seek to enjoin 'have already occurred and cannot be undone.' Accordingly, their claim for injunctive relief is moot." (citation omitted)).

Because we find that this case has become moot while on appeal, we vacate the judgment and order of the district court and remand with instructions that this action be dismissed. *See United States v. Munsingwear,* 340 U.S. 36, 39-41 (1950).

VACATED AND REMANDED WITH INSTRUCTIONS

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4. Appellants do not suggest that their request for "such actual damages as proved at trial," J.A. at 54, saves this appeal from mootness, and we indeed see no basis in the FACA for an award of damages.

APPENDIX C — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND DATED SEPTEMBER 26, 1994

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Civil No. PJM 94-1703

MARY DOE, et al.

Plaintiffs

v.

DONNA SHALALA, et al.

Defendants

OPINION

I.

Plaintiffs in this suit seek to enjoin the activity of the National Institutes of Health (NIH) Human Embryo Research Panel (Panel) on the grounds that the membership of the Panel is not "fairly balanced" within the meaning of the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2, 5(b) (2) and on the further grounds that Section 101 of the NIH Revitalization Act of 1993 (Revitalization Act), 42 U.S.C. §289a-1, violates the U.S. Constitution. More immediately, their objective is to prevent the Panel from holding any meetings or making any recommendations to NIH or the Secretary of Health and Human Services with regard to the issue of human fetal research. The matter comes before the Court in the form of a Motion for

Appendix C

Preliminary Injunction, anticipating the imminent publication by the Panel of its report and recommendations.

The Court holds that Plaintiffs lack standing to litigate these claims and, particularly insofar as the claims are based on the Federal Advisory Committee Act, that the matter is non-justiciable. Accordingly, the Court finds no need to engage in the usual preliminary injunction analysis and will proceed directly to dismiss Plaintiffs' suit.[1]

II.

Would-be Plaintiff Mary Doe is an unnamed baby girl who, according to the Amended Complaint, is "a pre-born child in being as a human embryo." She is allegedly one of more than 20,000 such embryos *ex utero* located in various in vitro laboratories within the United States. Plaintiff International Foundation for Genetic Research (The Michael Fund) is a non-profit organization whose primary purpose is to sponsor research involving the genetic disorder known as Down's Syndrome and

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1. The Court understands that Plaintiffs at this juncture seek only preliminary injunctive relief. Defendants, however, have filed a Motion for Judgment on the Pleadings or, in the Alternative for Summary Judgment, as to which Plaintiffs have filed an opposition. The issue of standing is, therefore, joined as to all aspects of the case. Moreover, standing necessarily inheres as a threshold issue whenever a party seeks relief in court, including preliminary injunctive relief. The Court has thus had to decide this issue without delay. Inasmuch as Plaintiffs have been held to lack standing for purposes of entitlement to preliminary relief, it is clear that they also lack standing to pursue any further relief in the case; hence the Court's dismissal of the suit.

Given the Court's decision of the standing issue, it becomes unnecessary to address, one by one, the conventional considerations for the issuance of a preliminary injunction.

similar inborn chromosomal disorders. Plaintiff Michael Policastro, after whom The Michael Fund was named, is 24 years of age and suffers from Down's Syndrome. Defendants, in addition to the Secretary of U.S. Department of Health and Human Services and NIH, are the Department of Health and Human Services, the Director of NIH individually, the NIH Human Embryo Research Panel and the individual members of the Panel.

The Panel whose activities are challenged in this proceeding came into existence following the enactment of the NIH Revitalization Act of 1993, P.L. No. 103-43, codified at 42 U.S.C. §281 et seq. Consideration of pertinent provisions of the Act will illuminate the nature of the litigation.

Under the Act, the Secretary of HHS may not withhold federal funds for clinical research "because of ethical considerations" unless she first convenes an ethics advisory board (EAB) which, in accordance with certain prescribed procedures, studies such considerations, and either (1) recommends, by majority vote, because of ethical considerations, that the Secretary withhold funds for their proposed research or (2) recommends, by majority vote, because of ethical considerations, that the Secretary *not* withhold funds for the proposed research, but the Secretary finds the recommendation to be arbitrary and capricious. *See* 42 U.S.C. §289a-1(b). This law amended existing federal regulations governing research on human embryos, which required such research to be reviewed by an EAB before such research might proceed. *See* 45 C.F.R. §46.204(d). Because prior presidential administrations apparently chose not to appoint an EAB, no funding for such research had in fact been approved. What the new law did was to reverse the conditions for in vitro fertilization research: it could

go forward unless disapproved. Previously it could not go forward unless approved.

Nothing in the new law appears to require the Secretary of HHS to appoint an EAB.[2] The law merely sets forth the procedures the Secretary must follow if and when she chooses to convene an EAB. Under the Act, she must first publish a statement in the *Federal Register* announcing her intention to convene the board, which must include a request that interested individuals submit recommendations "specifying the particular individuals who should be appointed to the advisory board involved." The Secretary must then consider these recommendations in making appointments to the EAB. *See* 42 U.S.C. §289a-1(b) (4) (A) and (B). The EAB must be composed of no fewer than 14 nor more than 20 members "who are not officers or employees of the United States" and who are "individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research." It must also be composed of at least one attorney, one ethicist, one practicing physician, one theologian, and no fewer than 1/3 but no more than 1/2, of "scientists with substantial accomplishments in biomedical or behavioral research." 42 U.S.C. §289a-1(b) (5) (C). An appointed member serves "for the life of the board" and can only be

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2. *See* 1993 Acts, Senate Report No. 103-2 in 1993 U.S. Code Cong. and Adm. News, p. 193, 214:

The committee further recognizes that there may be, from time to time particular research proposals for which ethical considerations have not been addressed to the Secretary's satisfaction by the institutional review boards and NIH's merit review system. For those cases, the committee provides a mechanism of convening ethics advisory panels to more fully address the Secretary's concerns. The committee has left to the Secretary the appointment of panel members, within certain guidelines.

removed by the Secretary "for neglect of duty or malfeasance or for other good cause shown." 42 U.S.C. §289a-1(b) (5) (D) and (E).

Not later than 180 days after an EAB is convened, it is required to submit to the Secretary and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the United States Senate a report describing its findings regarding the proposed research project or projects and making recommendations as to whether the Secretary should or should not withhold funds for such project or projects on ethical grounds. 42 U.S.C. 289a-1(b) (5) (B) (ii).

With the passage of the Revitalization Act, NIH in fact received a number of applications seeking financial support of research involving human embryos. During the fall of 1993, therefore, Secretary Shalala, acting pursuant to the law, decided to convene and appoint an EAB, to be known as the NIH Human Embryo Research Panel.[3] The Panel was charged by the Secretary with addressing the moral and ethical issues raised by the use of human embryos in research and with developing "guidelines" as to which areas of research involving human embryos would be acceptable for funding, which would require additional review, and which would be unacceptable for federal support. The Committee has held five public meetings all of which were open to the public and is expected to render a report to the Advisory Committee to the Director of NIH in short order.

In the present suit Plaintiffs seek to block issuance of the report and any further activities of the Panel, contending in part

3. The Government disputes that the Panel is either an "advisory committee" under FACA or an EAB under the Revitalization Act. The Court assumes for purposes of this Motion that the Panel is both.

that at least 10 of the 19 members of the Panel "are current or former NIH grantees who have firmly endorsed the principle and many of the protocols of extended and unfettered human embryo research." The Panel, say Plaintiffs, "is accordingly predisposed to and will most probably make recommendations in favor of the Secretary not withholding federal funding for at least some projects involving human embryo research."

If, Plaintiffs continue, the Panel makes recommendations in favor of the Secretary not withholding federal funding for proposed projects involving human research, Plaintiffs will be harmed in the following ways: would-be Plaintiff Mary Doe and the group of which she is a part will be deprived of "the right to life without due process of law"; Plaintiff The Michael Fund will have federal funding otherwise available to support research involving Down's Syndrome and related disorders diverted to projects involving human embryo research; and individual Plaintiff Michael Policastro will not only suffer the consequences of the Fund's reduced research support, but will, along with other mature persons affected with Down's Syndrome, be threatened with the loss of life by the activities of Defendants, "which will have the effect of making socially acceptable, and ultimately fully legal, the destruction of people affected with Down's Syndrome."

Plaintiffs challenge the existence and activities of the Panel in several counts. They contend:

— in Count I, that the lack of balance and conflicts of interest prevalent on the Panel violate the "fair balance" requirement of the Federal Advisory Committee Act, 5 U.S.C., App. 2, Section 5(b) (2);

— in Count II, that Section 101 of the Revitalization Act

violates Article II, Section 2, Clause 2, the Appointments Clause of the U.S. Constitution, which requires Presidential appointments of certain government officers;

— in Count III, that Section 101 of the Act violates Article II, Section 3 of the Constitution in that it restricts the President's power to take care that the laws be faithfully executed;

— in Count IV, that Section 101 violates the doctrine of separation powers; and

— in Count V, that the actions of Defendants violate the Fifth, Eighth, and Ninth Amendments to the Constitution, in that they will deprive would-be Plaintiff Mary Doe, others like her, and individual Plaintiff Michael Policastro, of life and liberty without due process of law, subject them to cruel and unusual punishment, and deprive them of their right to privacy.

Mindful of the imminent publication by the Panel of its report and recommendations to the Advisory Committee and the Secretary, Plaintiffs ask for a preliminary injunction to prevent the publication as well as a cessation of any further Panel activities pending trial.

In response, the United States argues primarily that the Panel is not an "advisory committee" subject to the Federal Advisory Committee Act, but only a group of consultants which will advise the Standing Advisory Committee of NIH, which in turn will advise the NIH Director. The Government also argues that Plaintiffs lack standing to pursue this suit and that certain issues are either non-justiciable or not ripe for decision. The Government opposes the issuance of a preliminary injunction.

The Court finds that considerations of standing and

justiciability are dispositive of the case. The Court therefore considers the applicable legal concepts.

III.

A) The Court accepts that organizational Plaintiff The Michael Fund and individual Plaintiff Michael Policastro properly speak for themselves through designated counsel. The situation is considerably different however, as to would-be Plaintiff Mary Doe, described as a "pre-born child in being as a human embryo." Putting aside for the moment the question of whether a human embryo has independent legal interests capable of protection, it is clear that any such interests would have to be protected through the person of a *guardian ad litem. See* Fed.R.Civ.P. 17(c); Cf. *Hatch v. Riggs National Bank*, 361 F.2d 559 (D.C.Cir. 1966) (proper to appoint guardian ad litem for unborn beneficiaries of trust). Indeed The Michael Fund has filed a motion that someone, presumably it, be appointed *guardian ad litem* of Mary Doe.

Ordinarily the inquiry with regard to appointment of a *guardian ad litem* would be limited to whether the guardian can adequately represent the interests of its ward. *Cf.* 42 Am.Jur.2d Infants, §179. Here, however, the matter is complicated by the fact that Mary Doe seeks to represent not only herself, but "all others similarly situated," which the Court understands to be some 20,000 human embryos currently in storage in various facilities around the United States. In other words, although The Michael Fund does not pray or plead it as such, it seeks to have this action proceed as a class action pursuant to Fed.R.Civ.P. 23.

There are several reasons why the suit cannot proceed as to "Mary Doe." First, philosophical and religious considerations aside, the Supreme Court has made it clear that the word

"person," as used in the Fourteenth Amendment, does not include the unborn. *Roe v. Wade*, 410 U.S. 113, 158 (1973). It has thus been held that embryos are not persons with legally protectable interests within the meaning of Fed.R.Civ.P. 17(c) such that appointments of *guardians ad litem* are warranted or required. *See Roe v. Casey*, 464 F.Supp. 483 (E.D.Pa. 1978), *aff'd* 623 F.2d 829 (3d Cir. 1980). The Court sees no distinction between fetuses *in utero* or *ex utero*.

Additionally, appointing a *guardian ad litem* for an unspecified embryo, much less for a class of some 20,000, would present the Court with an impossible task. While the Court in no sense questions the bona fides of The Michael Fund, it is asked to decide that The Michael Fund, which is apparently committed to the prevention of federal funding for fetal research, can fairly represent the interests of one unspecified fetus and 20,000 others. The Senate and House Reports on the Revitalization Bill, however, demonstrate that there is considerable sentiment — indeed a majority of both Houses of Congress — which directly opposes the position of The Michael Fund and which holds a distinctly different view regarding the benefits of human fetal research.[4]

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4. *See* 1993 Acts, Senate Report No. 103-2 in 1993 U.S. Cong. and Admin. News, p. 193, 209-210:

Scientists have been using fetal tissue for disease research since the 1950's. Fetal cells have been especially useful for the reproduction of human viruses to test drugs and vaccines. For example, cultured human fetal kidney cells were essential to growing the polio virus and the research that led to the development of the polio vaccine. Forty years ago, more than 50,000 people were afflicted with paralytic polio each year. Today, as a direct result of that research people throughout the world need not suffer from that disease.

* * *

(Cont'd)

Appendix C

Based on conventional considerations relating to the appointment of *guardians ad litem* and class representative, the Court declines to designate the organizational Plaintiff as *guardian ad litem* for would-be Plaintiff Mary Doe. The suit will not be permitted to go forward and will be dismissed as to her. The Court proceeds with its review of the standing of Plaintiffs The Michael Fund and Michael Policastro to pursue the litigation.

IV.

A) Under Article III, Section 2, of the U.S. Constitution, the judicial power of the United States extends to cases and controversies. The two terms, which are essentially interchangeable, *see Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937), refer to disputes which are "definite and concrete, touching the legal relations of parties having adverse legal interests. It must be a real and substantial controversy

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(Cont'd)

Clinical transplantation of fetal tissue is at the earliest stage of development. The purpose of the research is to determine if therapy with fetal tissue holds promise for the development of new treatments or cures for disease. Although the moratorium has thwarted research to answer this question, there is some preliminary evidence that indicates the potential for fetal tissue transplantation research. For example, fetal pancreatic tissue can make insulin for the treatment of diabetes and can become integrated in the control of the body's energy metabolism. Similarly, fetal brain tissue can produce the chemical messenger dopamine, which is lacking in Parkinson's disease.

* * *

This legislation . . . establishes rational and fair procedures to address ethical concerns with scientifically approved research projects. The measure is intended to prohibit unilateral actions that block research approved by the merit review system.

See also House Conf. Rep. No. 103-100, *Id.* at 287-288.

admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of affairs." *Id.*, 300 U.S. at 240-241.

One component of the case or controversy requirement is the question of standing, which bears on the power of a court to entertain a party's claim. *See Valley Forge Christian College v. Americans United*, 454 U.S. 464 (1982). Standing involves determining whether a particular litigant is entitled to invoke the jurisdiction of a court to decide a particular issue. *Id.* The focus is on the status of the party seeking to pursue the complaint; the party's arguments on the merits of the case are irrelevant to the determination. *Flast v. Cohen*, 392 U.S. 83, 99 (1968).

Although there has been some uncertainty about the scope of the standing doctrine in the past, it is essentially settled that:

> at an irreducible minimum, Art. III requires the party who invokes the court's authority to "show that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant," and that the injury "fairly can be traced to the challenged action" and "is likely to be redressed by a favorable decision." [Citations omitted]

Valley Forge Christian College at 472. The Court considers each of these elements.

With regard to the injury requirement, a party must have "such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation

of issues upon which the court so largely depends for illumination of difficult constitutional questions." *Baker v. Carr*, 369 U.S. 186, 204 (1962). The injury must be direct, distinct and palpable, not merely conjectural. *Allen v. Wright*, 468 U.S. 737, 751 (1984). It must be an "injury-in-fact." *Association of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 152 (1970). Mere interest in a problem, no matter how long-standing or how qualified the litigant, will not to satisfy the requirement. *McKinney v. U.S. Department of Treasury*, 799 F.2d 1544 (Fed. Cir. 1986). Nor will it do to allege injury to others which a plaintiff purports to represent. *U.S. Dept. of Labor v. Triplett*, 494 U.S. 715 (1990). Nor, finally, is it sufficient to argue that, if Plaintiff is not given standing, no one will be able to litigate an issue. *Valley Forge Christian College*, 454 U.S. at 489.

In addition to particularized injury, a plaintiff to have standing must also show that the injury concretely and demonstrably has resulted from defendant's action. *Simon v. Eastern Kentucky Welfare Right Organization*, 426 U.S. 26 (1976). In other words, in addition to injury-in-fact there must be causation-in-fact. The injury must be suffered "as a consequence of the alleged constitutional error," and must be "other than the psychological consequence presumably produced by observation of conduct with which one disagrees." *Valley Forge Christian College*, 454 U.S. at 482. An assertion of harm that is too speculative or remote will not suffice. *Laird v. Tatum*, 408 U.S. 1 (1972).

At the constitutional level, there is yet a third requirement for standing, *i.e.* that the injury is likely to be redressed by a favorable decision. *See Simon*, 426 U.S. 26 (1976). As the Supreme Court has instructed, there must be a "substantial likelihood" that the relief sought from the court, if granted, will remedy the harm. *See Duke Power Company v. Carolina*

Environmental Study Group, Inc., 438 U.S. 59 (1978); *Watt v. Energy Action Educational Foundation*, 454 U.S. 151 (1981).

B) Along with the Article III core constitutional standing requirements, certain "prudential" limitations exist with regard to the exercise of jurisdiction by a federal court. That is, principles of prudence may counsel the judiciary to refuse to adjudicate some claims, even when constitutional standing has been satisfied. *See Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91 (1979). The Supreme Court in *Valley Forge Christian College*, 454 U.S. at 474-475 identified three considerations as prudential ones:

1) A plaintiff's interest must come within the "zone of interest" arguably protected by the statute in question. *See Association of Data Processing Service Organizations, Inc. v. Camp*, 397 U.S. 150 (1970);

2) A plaintiff may not air "generalized grievances" shared by all or a large class of citizens. *See United States v. Richardson*, 418 U.S. 166 (1974); and

3) A plaintiff ordinarily may not assert the legal rights of others, unless the party has suffered an injury in fact, has a close relation to the third party, and there is some hindrance to the third party's ability to protect his or her own interest. *See Powers v. Ohio*, 499 U.S. 400 (1991).

C) Against this legal background, the Court considers Plaintiffs' claims in the present case.

The Court turns first to the issue of constitutional standing and the questions of injury-in-fact, causation-in-fact, and the redressability of any injury by a favorable court decision.

Appendix C

Plaintiffs The Michael Fund and Michael Policastro allege that injury to them will result because "federal funds available for the support of research designed to discover a cure and treatment for persons afflicted with genetic disorders, such as Down's Syndrome, will be reduced in direct proportion to the extent that such funds are diverted to the support of human embryo research projects." Michael Policastro is said to be threatened with the loss of his life because the activities of Defendants "will have the effect of making socially acceptable, and ultimately fully legal, the destruction of people with Down's Syndrome."

These allegations of injury, sincerely felt though they may be, do not, in the Court's view, pass constitutional muster. Such injuries are remote and speculative, not immediate and palpable. Even if, following a report of the Panel, NIH were to elect to fund fetal research projects (and it is by no means certain to what extent it will), there is no basis for concluding that that decision would diminish funding for research projects involving Down's Syndrome or other genetic disorders. Nor is there any basis in the least for suggesting that Plaintiff Michael Policastro's life might be at risk if fetal research were to go forward.

Similarly, Plaintiffs cannot satisfy the second constitutional requirement for standing — that there be causation between the challenged action and the particularized injury sustained. There is, again, simply no basis for concluding that an ultimate decision by NIH to fund fetal research would concretely and demonstrably diminish the organizational Plaintiff's funding or put Michael Policastro's life in danger.

Finally, it is open to serious question whether a court decree in this case would actually redress the alleged harm. What Plaintiffs ask for is injunctive relief to prevent the Human Embryo Research Panel from reporting to the Advisory

Committee and the Secretary about the ethics of pursuing human embryo research or, indeed, from carrying on any further activities. But preventing the Panel from issuing a report could well have no effect whatsoever on the ultimate decision of the Secretary to fund such research. The Revitalization Act allows that such research may go forward *unless* an EAB advises the Secretary that it should not and if she does not overrule the Panel. In sharp contrast to prior law, there is no requirement that an EAB be constituted at all before the research proceeds. In other words, it may be doubted — for constitutional purposes — whether blocking the Panel's report or its other activity would fairly redress the harms claimed here if the Secretary of HHS decided to go forward with funding in the absence of a report from EAB and with the activities of the Board frozen by injunction. *See Public Citizen v. Dept. of Health and Human Services*, 795 F.Supp. 1212 (D.C.D.C. 1992) (relief sought by plaintiff in striking recommendations of "unbalanced" FACA committee held unlikely to redress plaintiff's claimed injury).

The Court concludes that Plaintiffs fail to meet the requisite constitutional requirements for standing to pursue this case.

D) Plaintiffs also fail to satisfy the prudential considerations of standing. They have sustained no injury within the "zone of interest" created by the executive order setting up the Panel; they are in fact airing generalized grievances of interest to citizens as a whole; and they are not able to assert the constitutional rights of others. In particular as to this last, as the Court has already noted, the Supreme Court has clearly foreclosed any legal conclusion that human embryos are "person" with constitutional rights to be protected. Beyond that, there has been no injury-in-fact to Plaintiffs, nor is there any sense in which Plaintiffs stand in a closer relationship to the

putative third parties, *i.e.* human embryos, than any other citizen might.

The Court is ultimately guided by the overriding policy of prudential limitations: that the judiciary should seek to avoid deciding questions of broad social import where no individual rights would be vindicated. *See Gladstone, Realtors v. Bellwood*, 441 U.S. at 99. The issue of fetal research is undoubtedly one of the broadest social importance. But prudential limitations are "founded in concern about the proper — and properly limited — role of the Courts in a democratic society." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). Plaintiffs present no concrete injuries particular to themselves which can be addressed in this suit. A federal court has no role to play in the resolution of the questions Plaintiffs seek to have decided.

V.

With regard to Count I of the Amended Complaint, there is a further reason besides lack of standing why this case cannot proceed. In the Court's view, the matter is non-justiciable.

Plaintiffs argue in that count that the Human Embryo Research Panel is not "fairly balanced in terms of the points of view represented and the functions to be performed," as required by Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2, Section 5(b) (2). In particular, they contend that the Panel is biased in favor of proponents of human fetal research. The Government's most telling reply is that, in view of the lack of judicially manageable standards to review the "fair balance" requirement, the matter is non-justiciable and for that reason the claim must be dismissed.

Appendix C

In its broadest sense, "justiciability" refers to all the circumstances appropriate for resolution of issues by courts. The Supreme Court in *Flast v. Cohen*, 392 U.S. 83 (1968) provided this definition:

> Embodied in the words "cases" and "controversies" are two complementary but somewhat different limitations. In part those words limit the business of federal courts to questions presented in an adversary context and in a form historically viewed as capable of resolution through the judicial process. And in part those words define the role assigned to the judiciary in a tripartite allocation of power to assure that the federal courts will not intrude into areas committed to the other branches of government. *Justiciability* is the term of art employed to give expression to this dual limitation placed upon federal courts by the case-and-controversy doctrine. (Emphasis supplied)

392 U.S. at 94-95.

Standing, which considers at whose behest adjudications may be made, is simply an aspect of the broader concept of justiciability. But justiciability also comprehends such questions as: When may courts decide issues? At what stages of a dispute? As to what issues? *See generally* Gunther, *Constitutional Law* (12th ed. 1991), p.1590 et seq.

Defendants' claim of non-justiciability as to Count I in the present case concerns the last of these questions, *i.e.* what issues will a court decide? And what Defendants argue is that federal

courts have specifically determined that they will not decide cases where, as here, the allegation is that a governmental advisory committee under the Federal Advisory Committee Act is not "fairly balanced" in its composition.

Defendants are correct. The balance of judicial opinion holds that, by reason of the lack of judicial standards to address alleged "imbalances" of membership on such committees, Courts will not decide the issue; it is non-justiciable. *See e.g. Metcalf v. Nat'l Petroleum Council*, 553 F.2d 176 (D.C. Cir. 1977); *Public Citizen, et al. v. Nat'l Advisory Committee on Microbiological Criteria for Foods, et al.*, 886 F.2d 419, 425 (D.C. Cir. 1989) (Silberman, J. concurring); *Public Citizen v. Dept. of Health and Human Services*, 795 F.Supp. 1212 (D.C.D.C. 1992). *But see Nat'l Anti-Hunger Coalition et al. v. Executive Committee of the President's Private Sector Survey on Cost Control*, 557 F.Supp. 524 (D.C.D.C. 1993), *aff'd* 711 F.2d 1071 (D.C. Cir. 1983). *Public Citizen v. Dept. of Health and Human Services* presents the basic rationale:

> Section 10(a)(2) of the APA [Administrative Procedure Act] bars judicial review of agency action when the action is "committed to agency discretion by law." Under *Heckler v. Chaney*, 470 U.S. 821, 84 L.Ed.2d 714, 105 S.Ct. 1649 (1985), agency action is committed to agency discretion by law when Congress has provided no "meaningful standard against which to judge the agency's exercise of discretion." *Id.* at 830.
>
> In the case now before the Court, there are no meaningful standards by which the Court can review whether the FDA Advisory

> Committee is "fairly balanced in terms of the points of view represented and the functions to be performed." The Committee's purpose is to examine "the mission, responsibilities and structure of the FDA according to its legislative mandate and to make recommendations on how the Agency can be strengthened to fulfill its mission." Charter of the FDA Advisory Committee. This is a broad purpose for which there is no doubt a broad range of viewpoints. For the Court to become entangled in determining which viewpoints must be represented is for the Court to arbitrarily substitute its judgment for that of the agency. No meaningful standards are available to assist the Court in making such political and ideological determinations.

795 F.Supp. at 1220-21.

Judge Silberman elaborated these concerns in *Microbiological Criteria*:

> The relevant points of view on issues to be considered by an advisory committee are virtually infinite and, therefore, the judgment as to what constitutes an appropriate or "fair" balance of those views must be a political one. This kind of a decision is very similar to the one a chairman of a congressional committee must make when he or she determines which witnesses should be called to testify about proposed legislation. Thus, even before the points of view on an advisory

> committee can be balanced at all — "fairly" or otherwise — it must first be determined which points of view should be balanced. And I can conceive of no principled basis for a federal court to determine which among the myriad points of view deserve representation on particular advisory committees.

886 F.2d at 426.

The Court agrees with Judge Hogan's opinion in the *Public Citizen* and Judge Silberman's in *Microbiological Criteria*. The mission of Human Embryo Research Panel's mission in this case is extremely broad to consider all possible areas of research involving the extracorporeal human embryo and to provide advice as to each. The Court sees "no principled basis" upon which it could determine which among myriad points of view deserve representation on the Panel. Meaningful standards to make such "political and ideological determinations" are altogether lacking. The concerns of this suit properly belong before the executive and legislative branches of government, not the judicial.

A separate Order will be entered implementing the Court's decision.

s/ Peter J. Messitte
PETER J. MESSITTE
UNITED STATES DISTRICT JUDGE

September 26, 1994

APPENDIX D — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND DATED SEPTEMBER 26, 1994

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Civil No. PJM 904-1703

MARY DOE, et al.

Plaintiffs

v.

DONNA SHALALA, et al.

Defendants

ORDER

Upon consideration of Plaintiffs' Motion for Appointment of a *Guardian Ad Litem* for would-be Plaintiff Mary Doe and Defendant' Opposition thereto; and upon consideration of Plaintiffs' Motion for Preliminary Injunction and Defendants' Opposition thereto; and upon consideration of Defendants' Motion for Judgment on the Pleadings or, in the Alternative, for Summary Judgment and Plaintiffs' Opposition thereto; it is for the reasons set forth in the Court's Opinion of even date, this 26th day of September, 1994

ORDERED that Plaintiffs' Motion for Appointment of a *Guardian Ad Litem* is hereby DENIED; and it is further

Appendix D

ORDERED that Plaintiffs' Motion for Preliminary Injunction is hereby DENIED; and it is further

ORDERED that Defendants' Motion for Summary Judgment is hereby GRANTED and Plaintiffs' Complaint and Amended Complaint are hereby DISMISSED.

s/ P. Messitte
PETER J. MESSITTE
UNITED STATES DISTRICT JUDGE

APPENDIX E — HHS MEMO DATED OCTOBER 20, 1993

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

[STAMP]
OCT 20, 1993

TO: Addressees

FROM: Sandy Chamblee, J.D. s/ Sandy Chamblee
Senior Policy Advisor and Counselor to the Director, NIH

SUBJECT: Internal Steering Committee for the Development of Human Embryo Research Guidelines

I am writing to invite you to serve on an internal steering committee that has been formed to assist in the planning of an initiative to develop guidelines for human embryo research. With the concurrence of the Assistant Secretary for Health, the Acting Director, NIH has initiated the formation of a broad-based panel to develop and recommend guidelines for Federal support of human embryo research (Tab A). The panel will be organized as a subcommittee to the Advisory Committee to the Director, NIH.

The internal steering committee's role in this initiative will involve proposing the composition and structure of the panel; establishing the scope, process, and timetable for its work; and, formulating an approach and framework for the consideration of the ethical issues and questions in this area of research. The

Appendix E

membership of the internal steering committee is provided at Tab B.

The first meeting of the steering committee will be held Friday, October 29, 1993, from 10:00 a.m. to 11:00 a.m. in Building #1, Room 151. If you have any questions before the meeting, please contact me on 6-2122 or Ms. Sarah Carr at 6-1454. Thank you.

Attachment (Tabs A and B)

Addressees:
Dr. Alexander, Dr. Baldwin, Dr. Dayton, Dr. Drage, Dr. Ellis, Dr. Juengst, Dr. McClure, Ms. Miers, Dr. Pinn, Dr. Shaikh, Ms. Whalen

APPENDIX F—HHS LETTER DATED DECEMBER 8, 1993

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Identical Letter Sent to All Panel Members

December 8, 1993

NOTE TO DR. MURRAY

Subject: NIH Human Embryo Research Panel

The NIH is tremendously appreciative of your willingness to serve on the Human Embryo Research Panel and will be sending a formal letter of appointment to you as soon as the entire panel is constituted. Because several weeks have passed since we first spoke about the Panel, I wanted to touch base and let you know that we hope to finalize panel membership by the third week of this month. A tentative first meeting date of January 27-28, 1993 has been set, but this is subject to change depending on Panel members' availability. Please let me know if this date is problematic for you.

I also want to let you know that advisors to the Federal government, even those serving in an ad hoc capacity, are required to complete a confidential financial disclosure report. I was unaware that this rule applied to ad hoc panel members when we spoke and want to be sure that you have advance notice of the requirement. The necessary paperwork will be sent to you with the appointment letter.

Appendix F

We will need to have a copy of your curriculum vita and a brief (one-page) narrative biography. I would appreciate your sending these to me at NIH, 9000 Rockville Pike, Building #1, Room 218, Bethesda, Maryland 20892.

If you have any questions about any of these matters, please contact me at 301-496-1454 (voice) or 301-402-0280 (facsimile). Thank you.

s/ Sarah Carr
Sarah Carr
Division of Science Policy
Analysis and Development
Office of the Director, NIH

APPENDIX G — EXCERPTED PAGES 96-98 OF HEARING OF NIH HUMAN EMBRYO RESEARCH PANEL DATED FEBRUARY 3, 1994

* * *

[96] **DR. MULLER:** Ms. Aronson.

MS. ARONSON: I'm puzzled with how we might structure seeking information and concerned and wondering about our responsibility to address whether this research should happen at all. This [97] mandate is that it's going to happen and the sort of charge of the panel was to develop guidelines. Is it that we're seeking specific guidelines from the public on what we want to see happen with this research, or are we just saying, let us know what you think about human embryo research?

DR. MULLER: I'm glad you raised that, because that came up in a preliminary meeting and it came up at lunch today, so let's talk about it for a second.

Yesterday one of the people who testified before us said that this panel was stacked, that we all already were sort of what the French call "parte-prix," it was not really a representative panel. To some degree, that's true because this panel was openly convened by the National Institutes of Health. I'm referring to our charge, but I won't read it. You can all look at it.

The fact is that there are people who are doing human embryo research. We've heard that because there's no federal funding for it at the moment, they're doing it often in proprietary institutions, and that, in the opinion of our friend yesterday, it's of very low quality, especially when compared to research abroad of this kind, which is legitimately funded and is done by more qualified, certified, et cetera, institutions.

Appendix G

There is research going on. There are scholars and scientists who want to do this research. It is now possible for the National Institutes of Health, which could not respond to any applications, to fund that research legally, but in order to so, they have quite appropriately said, hey, we need some guidelines. We're just not going to fund anybody who wants to do embryo research.

They said probably in this area there are some things that ought to be done, and we ought to know what, in the opinion of a good panel, these things are. There are probably some things that definitely ought not to be done, and we ought to know what those are. Then, because the panel consists of human beings and will have limited time and are not geniuses, and they may not even be all that arrogant, and they may be cowards, then there's got to be an area in between which bears further study, which means if there are issues that we can't agree on or that we feel we don't have enough information on, we can punt. We can say, yes, this kind of thing ought to be done, that kind of thing ought not to be done; and here are some things where we don't know yet whether they ought to be done or not. They require further study.

There is presumably nobody on this panel who believes that there ought to be no federally funded human embryo research at all, because if that's what you believed; that would have been a good reason to say, no, I don't want to serve on such a panel. I don't think there should ever be any research on the human [98] embryo.

Where we have to focus is on the question of, if the NIH is going to fund human embryo research, where are the areas where we feel comfortable that research is appropriate, in what conditions, et cetera? Where are the areas where we're quite sure that this should not be done, and are there areas in between where we're

divided among ourselves or we feel we lack the information or we, for various reasons, believe that we can't say yea or nay, all we can do is look at this some more?

Does that help?

MS. ARONSON: So you're saying we don't have any responsibility to be handling the negative view of human embryo research? Because that determines some of our public testimony.

DR. MULLER: If by negative you mean a view that there should be no human embryo research whatsoever, I guess my response would be yes, but even in some of the most negative testimony that we heard, no one said there should be no human embryo research. They talked about applying the same conditions that apply to functioning humans and so on.

So I don't think we have to take a view into account that there should be no human embryo research, period. I think we have to think very carefully about what kind.

Okay. Anybody else on this point? I think if we could get a list of the organizations that have been written to and the letter, and if we accept the fact that we're free to encourage other people to testify, and if we accept the fact that there will be if not national media publicity, then specialized media publicity and so on, maybe that's as far as we can go with this.

Dr. Murray.

* * *

APPENDIX H — BALTIMORE SUN ARTICLE DATED DECEMBER 3, 1994

Clinton limits embryo-research funds

Ban aimed at those created for lab work

Associated Press

BETHESDA — President Clinton yesterday ordered that no federal funds be spent on human embryos created for research purposes only.

But Mr. Clinton did not specifically forbid federal financial support for research on human embryos that originate from in vitro fertilization — the so-called test tube baby technique.

"I do not believe that federal funds should be used to support the creation of human embryos for research purposes," Mr. Clinton said. His order yesterday was far less sweeping than previous restrictions imposed by Presidents Ronald Reagan and George Bush.

"I have directed that the National Institutes of Health not allocate any resource" for studies of human embryos that were created for research purposes.

Dee Dee Myers, the White House press secretary, said Mr. Clinton's terse statement "should be interpreted very narrowly."

Asked if the statement would permit federally financed research using embryos that were surplus from in vitro fertilization clinics, she said, "The president's statement doesn't outlaw that."

Appendix H

In his statement, Mr. Clinton said that research on fertilized human eggs "raises profound ethical and moral questions as well as issues concerning the appropriate allocation of federal funds."

The report of the NIH's human embryo committee said the research had the potential of finding new ways to correct infertility, to improve methods of avoiding or correcting birth defects, and to learn fundamental cell biology that might lend itself to combating cancer.

After studying the issue for nine months, the committee delivered its recommendations this week to another panel that advises Dr. Harold Varmus, the NIH Director.

That panel endorsed the recommendations, leaving the final decision up to Dr. Varmus — until President Clinton took it out of his hands.

Mr. Clinton praised the work of the committees and said he understood how the research could make advances in in vitro fertilization, the so-called test tube baby technique. He also said he planned to establish a bioethics advisory commission to further deliberate such issues.

The advisory committee acknowledged that many people had ethical and moral reservations about its recommendation.

Under its the recommendation, embryo research would have been subject to strict controls, including limiting it to the first 14 days after fertilization. At that point, a fertilized human egg has grown to hundreds of cells but has not yet developed a nervous system, specific tissue or a human form.

Appendix H

The White House announcement came as opponents of human embryo research, mostly groups that also oppose abortion, were gathering forces for a showdown in Congress. A coalition of the opponents planned a news conference Monday and one congressman already had pledged to support their efforts with legislation.

'Frankenstein' experiments

"Regardless of any potential medical advancements, human dignity must not be degraded by having life created in a laboratory dish just to have it thrown out with the trash when scientists are finished with their Frankenstein-type experiments," said Rep. Robert K. Dornan, R-Calif., who promised to carry the fight to Congress.

Richard Doerfinger of the U.S. Catholic Conference said his organization would support efforts to block federal funds for embryo research.

Guidelines for embryo research were first recommended by an NIH committee in 1979, but President Reagan and President Bush opposed it and the process withered. Dr. Varmus, who was appointed by President Clinton, revived the effort by naming the embryo research committee earlier this year.

Despite the lack of federal funds, clinics and universities that provide in vitro fertilization services — the so-called test-tube-baby technique of assisting reproduction for infertile couples — have privately financed extensive research for more than a decade.

Appendix H

'Public has not idea'

Dr. Steven Muller, president emeritus of the Johns Hopkins University and chairman of the embryo advisory panel that studied the issue for months, said members of that committee received more than 50,000 pieces of mail, most of it protesting government support for the research.

"The public has no idea what human embryo research means, but to most people it does seem terrible." Dr. Muller said. "The extreme high level of public ignorance invites exploitation" by opponents to the research.

Dr. J. B. Younger, medical director of the American Society for Reproductive Medicine, said that by studying the developing embryo, which is a rapidly growing mass of cells, science could learn much about cancer, which also can be a rapidly growing mass of cells.

"Once you understand the fundamentals of what's normal growth, such as in an embryo, then you can learn how to prevent what is abnormal, such as cancer," he said.

APPENDIX I — WASHINGTON POST ARTICLE DATED OCTOBER 2, 1994

C6 SUNDAY, OCTOBER 2, 1994

The Washington Post

AN INDEPENDENT NEWSPAPER

Embryos: Drawing the Line

THE PANEL OF 19 experts charged by the National Institutes of Health to advise the government on human embryo research made a conscientious effort to answer a question fraught with difficulties both moral and scientific: Should the government fund research that involves creating, then destroying, human embryos for research purposes alone? But its conclusion — that, under certain strict guidelines, the government should — is in our view flat wrong. The creation of human embryos specifically for research that will destroy them is unconscionable. The government has no business funding it.

Viewed from one angle, this issue can be made to yield endless complexities: What about the suffering of individuals and infertile couples who might be helped by embryo research? What makes this different from the use of "extra" embryos left over from couples' fertility work-ups? What about the need to police this research where it is already being done? What is the status of the brand-new embryo? But before you get to these questions there is a simpler one: Is there a line that should not be crossed even for scientific or other gain, and if so where is it?

Some believe — we do not — that the line should be drawn before contraception, which prevents a possible conception, or abortion, which destroys an unintended conception, or research

on fetal tissue resulting from abortions. Opponents of abortion have so far been cited as the main opposition to the embryo recommendations, and they have pledged to ask Congress to block the recommendations by ruling on when life begins.

But it is not necessary to be against abortion rights, or to believe human life literally begins at conception, to be deeply alarmed by the notion of scientists' purposely causing conceptions in a context entirely divorced from even the potential of reproduction. One panelist, Georgetown law professor Patricia King, wrote as much in a partial dissent, saying society has not yet "developed a conceptual framework to guide us" when "human life is being created solely for human *use*." To suggest that support for abortion rights equals support for such experimentation is to buy abortion opponents' view that permitting abortion means erasing society's ability to make distinctions.

Though the panel of experts said a developing embryo merits "serious moral consideration," they concluded that the moral status of embryos younger than 14 days (when the first "primitive streak" heralds the beginning of the nervous system) is not equal to that of more-developed embryos or human infants. Some members, it's reported, initially wanted to use three weeks, the point at which brain formation begins — a fair index of the subject's slippery-slope potential.

Much of the report is useful. Embryo research is already a common byproduct of the burgeoning study and practice of in vitro fertilization and is legal in Canada and elsewhere. It's important to put ethical guidelines in place if the government is to fund anything in this area. The panel would prohibit cloning or the use of embryos past 14 days; it restricts embryo creation to

Appendix 1

"compelling" projects and to cases where grant-seekers can show (1) that the same questions cannot be answered with existing embryos, or (2) that new ones are needed for "scientific validity." It's the second of these categories, not the first, to which Ms. King dissents. But we find both alarming. In approving the funding of the purposeful creation of human embryos for *any* experiments the panel took a step too far.

APPENDIX J — THREE AFFIDAVITS IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CIVIL ACTION NO.
PJ-94-1703

MARY DOE, preborn child, et. al.,

Plaintiffs

DONNA SHALALA, et. al.,

Defendants

AFFIDAVIT IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, the undersigned reside at RD#3, Export, Westmoreland County, Pennsylvania.

STATEMENT

In 1978, I co-founded with Dr. Jerome Lejeune, Chair, Department of Fundamental Genetics, University of Paris, France, the International Foundation for Genetic Research, popularly known as The Michael Fund.

For the past seventeen years, The Michael Fund has financed the Down Syndrome medical research program conducted in Paris under the direction of Dr. Lejeune and his staff. The Pittsburgh-based office of The Michael Fund also operates a national referral service in the areas of adoption of mentally and/or physically handicapped children, early intervention and

developmental programs for Down Syndrome children, and informed consent regarding the dangers to mothers and children of various forms of non-therapeutic, prenatal diagnostic techniques such as fetoscopy, mid-trimester amniocentesis, and chorion villus sampling (CVS).

Since its founding The Michael Fund has been an international advocate for the rights of all mentally retarded and/or handicapped children, born and preborn. We stand opposed to all forms of discrimination against these, the least of our kin, born and preborn, most especially lethal forms of discrimination such as eugenic abortion before birth and murder by injection after birth.

This lethal discrimination cannot help but be expanded by the Human Embryo Research Panel's endorsement of tax-funded preimplantation genetic screening programs described by Lori B. Andrews, J.D. an invited presenter at the first Panel hearings on February 2, 3, 1994.

As an international genetics research agency whose motto is "Attack birth defects, not those who have them," The Michael Fund has forthrightly opposed the eugenic trends in the field of genetics and sociobiology. In the early 1980s the ratio of dollars spent on to non-therapeutic, first and second trimester programs of prenatal diagnosis combined with selected abortion of affected preborn children compared to curative/therapeutic research and treatment of Down Syndrome and related chromosomal disorders compared was about 100 to one. The Panel's endorsement of federal tax funding of preimplantation genetic screening programs will up the ante against the Down Syndrome preborn child and his brothers and sisters who manage to escape the ever broadening eugenic net.

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The Michael Fund is also concerned that extra-uterine manipulation of babies conceived by invitro fertilization (IVF) will lead to an increase in birth defects, as well the dangers of ovarian cancer posed to women exposed to various superovulating drugs in connection with infertility treatment.

The manner in which the Human Embryo Research Panel was selected by an ad hoc Steering Committee of NIH Director Varmus and NIH institutional officers, made it impossible for The Michael Fund to participate in the membership selection process or to participate in the formative stages of the Panel's organization and direction of its assigned mission and proposed research areas. By the time of the first official public notice of the existence of the Human Embryo Research Panel in the *Federal Register* of Friday, January 14, 1994, Vol. 59, No. 10, p.2414, the membership and direction of the Panel had already been established. Giving The Michael Fund, which opposes the types of destructive human embryo research the Panel is considering for tax-financing, and which supports the federal funding of truly therapeutic and curative research for affected children, born and preborn, the opportunity for making oral statements *not to exceed five minutes* at Panel meetings where public testimony is heard and routine Panel business is carried on, does not compensate for the lack of opportunity to have had input into the origins of the Panel's creation and its mission and direction.

I verify under penalty of perjury that the foregoing is true and correct.

s/ Rosemarie Engel

Date: August 12, 1994

Appendix J

State of:
County of:

Sworn to and before me this
12 day of August, 1994
s/ Dolores J. Tedjeske Notary Public
My commission expires:

[Seal]
Notarial Seal
Dolores J. Tedjeske, Notary Public
Washington Twp., Westmoreland County
My Commission Expires May 10, 1997
Member, Pennsylvania Association of Notaries

Appendix J

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CIVIL ACTION NO.
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MARY DOE, preborn child, et. al.,

Plaintiffs

v.

DONNA SHALALA, et. al,

Defendants

AFFIDAVIT IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, the undersigned, reside at 760 Highland Avenue, Needham, County of Middlesex, Massachusetts.

My name is Joseph R. Stanton, M.D. F.A.C.P. For many years I was a visiting Physician at St. Elizabeths Hospital in Brighton, Massachusetts and Associate Clinical Professor of Medicine at Tufts University School of Medicine. Since 1985 I have been retired from the active practice of medicine but continue to write and speak on medical ethical subjects. Indeed I have spoken and written articles on the subject of human fetal research, and in fact submitted a formal statement to the current NIH Human Embryo Research panel.

I am concerned about the longterm and documented pro-

abortion bias of Panel Member Dr. Kenneth Ryan, M.D. to wit; the original pro-abortion briefs in Roe v. Wade according to the signed letter of Dr. Allan Barnes, M.D. President of the Association for the Study of Abortion (ASA) 3/3/71 were "sponsored by the Association for the Study of Abortion and the James Madison Constitutional Law Institute" under Roy Lucas Esq. who was also on the Board of the Association for the Study of Abortion. This The Association for the Study of Abortion when Roe v. Wade came down — proclaimed it as "the decision sought by ASA since its foundation in 1964 virtually our organizational raison d'etre." (cf. Presidents letter dated January 1973) It promptly disbanded after Roe v. Wade and Doe v. Bolton were handed down. 100 professors of Obstetrics responded to the A.S.A.'s Dr. Barnes and this resulted in 2 events a) A "statement on abortion by 100 professors of obstetrics" American Journal of Obstetrics and Gynecology April 1, 1972 which include the remarkable statement;

> "- - - It will be necessary for physicians to realize that abortion has become a predominently social as well as medical responsibility. For the first time except perhaps for cosmetic surgery doctors will be expected to do an operation simply because a patient asks that it be done. Granted this shanges medicines traditional role but it will be necessary to make this change as we are to serve the new society in which we live."

b) The Pro-Abortion brief of the American College of Obstetrics and Gynecology, The American Psychiatric Association, The American Medical Womens Association, The New York Academy of Medicine and a group of 178 physicians as Amici

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Curia in Roe et. al., v. Henry Wade, Supreme Court of The United States, October Term 1970, No. 78-18 Dr. Kenneth Ryan was a prominent signatory of both a and b. In neither published item was the pro-abortion sponsorship by A.S.A. acknowledged.

In JAMA*233* pg. 781, 1975 Dr. Ryan wrote: "The medical profession should provide leadership in developing — access to early abortion." He has published papers on abortion including prostaglandin induced abortions which can result in the delivery of a living fetus and has accepted grants from NIH and The March of Dimes for abortion research "Fertility after Induced Abortion; A Prospectus follow up study. Obstet & Gynecology 186-193, 1984.

Dr. Ryan indeed has served on prior Health and Human Services and NIH panels - in 1975 and 1988. On both of these the public records shows he awas committed to and voted in favor of non-therapeutic research on the deliberately aborted human embryo and fetus. Dr. Kenneth Ryan's appointment to the current N.I.H. Human Embryo Research Panel brings substantial and undeniable bias to a panel whose charge (Lecter of Duane Alexander, Director National Institute of Child Health and Development dated 2/18/94) is to address "the profound moral and ethical issues raised by the use of human embryos in research."

s/ Joseph R. Stanton, M.D.
Joseph R. Stanton, M.D. F.A.C.P.

I verify under penalty of perjury that the foregoing is true and correct.

Date: 8/11/94

Joseph R. Stanton
(Name)

Appendix J

State of: Massachusetts

County of: Middlesex

Sworn to and before me this
11th day of August, 1994

s/ Dorothy Bennett NOTARY PUBLIC
My commission expires: March 13, 1998

Appendix J

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CIVIL ACTION NO.
PJ-94-1703

MARY DOE, preborn child, et. al.,

Plaintiffs

v.

DONNA SHALALA, et. al,

Defendants

AFFIDAVIT IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, the undersigned reside at RD#3, Export, Westmoreland County, Pennsylvania.

STATEMENT

The following information on NIH grant titles and abstracts [period from 1987 to the present] awarded to individuals currently serving on the NIH Human Embryo Research Panel was obtained from the National Institute of Health's CRISP system by researcher Suzanne Rini at the request of The Michael Fund.

Panel members include:

Kenneth J. Ryan, M.D.

Appendix J

Dorothy Nelkin
Thomas H. Murray
Mary C. Martin, M.D.
Bernard Lo
Mark R. Hughes, M.D., Ph.D.
Brigid Hogan, Ph.D.
Fernando A. Guerra, M.D., M.P.H.
Andrew G. Hendrickx*
Patricia Donahue*

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* Patricia K. Donahue, 1991 NIH grant for $681,000 titled, "Mullerian Inhibiting Substance."

* Andrew G. Hendrickx, PH.D., 1991 NIH grant for $539,000 for "Maintenance of a Non-Human Primate Breeding Colony." This colony was established and is run by the NIH.

Appendix J

Kenneth J. Ryan, M.D.
Chair, Ethics Committee, Brigham & Women's Hospital; Distinguished Professor, Dept. of Obstetrics and Gynecology, Harvard University School of Medicine

NOTE: Dr. Ryan works with the Center for Population Research, an NIH project. His NIH grants are as follows:

1987

(1) $783,586 TITLE: Center for Population Research
ABSTRACT: "The proposed research plan is to operate a Center for Population Research within the Laboratory of Human Reproduction and Reproductive Biology to foster the acquisition of knowledge that can ultimately be applied to the control of fertility and the reduction of reproductive disease and disability. . . . This work is carried out largely in material derived from mammals (including the human) applicable to human biology.

(2) $224,262. TITLE: Steroid Hormone Metabolism (Harvard University)
ABSTRACT: ". . . The proposed research research will help us understand basic mechanisms involved in ovarian function, specifically atresia, blood vessel dynamics and neuroendocrine control of the ovary. . . ."

(3) $633,396 TITLE: "Center for Population Research"
ABSTRACT: See 1987 above under same title.

(4) $213,313 TITLE: "Steroid Hormone Metabolism"
ABSTRACT: See 1987 above under same title.

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1989

(1) $657,852 TITLE: "Center for Population Research"
ABSTRACT: See 1987, 1988 above under same title.

1990

(1) $720,933 TITLE: "Center for Population Research"
ABSTRACT: See 1987, 1988, 1989 above under same title.

1991

(1) $672,404 TITLE: "Center for Population Research"
ABSTRACT: As above.

1992

(1) $91,842 TITLE: "Center for Population Research"
ABSTRACT: As above.

TOTAL: $3,997,648

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Dorothy Nelkin
Professor of Sociology
New York University

1991

(1) $109,814 TITLE: "Human Heredity in American Popular Culture"
ABSTRACT: "This study will explore the meaning of human genetics in popular culture, placing contemporary view within the context of changing ideas about heredity and eugenics since the turn of the century . . . What images are used to describe the nature of human heredity? What can these images reveal about the diverse way 'consumers' of genetic information can be expected to use and interpret that information? These images help us understand the popular ideas that will utimately affect human relationships, social policies and health care decisions, as well as public receptivity to future genetics research."

1992

(1) $96,290 TITLE: "Human Heredity in American Popular Culture"
ABSTRACT: See above.

1993

(1) $173,279 TITLE: "Human Heredity in American Popular Culture"
ABSTRACT: See above.

TOTAL: $380,383

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NOTE: Genetics and developmental embryology (embryo research) are interlinked. See NIH booklet Developmental Biology, Genetics and Teratology Branch, Report to Council, January, 1994. Available from Suzanne Rini upon request.

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Thomas H. Murray
Director for Biomedical Ethics
Case Western Reserve University
School of Medicine

1991

(1) $70,176 TITLE: "The Human Genome Initiative and Access to Health Care."
ABSTRACT: ". . . This project is intended to provide an overview of the Genome Project's impact on access to health care by engaging 13 leading scholars in research on specific topics within their expertise and extending that research to address the impact of the Genome Project." . . . [A book from this project] will incorporate studies of reimbursement, employer health benefits, and the distribution of scarce medical resources . ."

1992

(1) $18,060 TITLE: "The Human Genome Initiative and Access to Health Care."
ABSTRACT: See above.

See Note on Nelkin

TOTAL: $88,236

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Mary C. Martin, M.D.
Associate Professor
Director, IVF Program, Dept. of Obstetrics, Gynecology
and Reproductive Science,
School of Medicine, University Of California,
San Francisco

1988

(1) $51,000 TITLE: "General Clinical Research Center:
SUB-TITLE: "Endocrine Definition & Neuroendocrine Modulation of Athletic Amenorrhea"
ABSTRACT: ". . . Evidence is presdented suggesting that, in patients with [hereditary fructose intolerance], fructose exposure induces dysfunction detectable by increased rates of lysomsomal residual body exrection in the urine. If found, this dysfunction ffers the possibility of heterozygote [carrier] identification and the possibility of elucidation of patheogenetic mechanisms relative to a broad range of metabolic disease."

TOTAL: $51,000

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Bernard Lo, Director,
Program in Medical Ethics, University of California,
San Francisco

1987

(1) $64,544 TITLE: "Variability in 'No Code' Orders Among Very Ill Patients"
ABSTRACT: "During the last decade, a consensus has emerged among physicians, legal experts, and ethicists that 'do not resuscitate' 9DNRO orders (also called 'no code' orders) are appropriate under certain circumstances. Specifically, patients with serious illnesses should make shared decisions with their physicians regarding intensive care and cardiopulmonary resuscitation. Despite this consensus, however, our pilot study suggests that these principles are being applied inconsistently. Our present study will attempt to confirm or refute this impression by determining the frequency of DNR orders for patients with four common diseases with similar prognoses: lung or colon cancer with distant metastates; acquired immunodeficiency syndrome (AIDS); cirrhosis of the liver with a history of esophageal varices; and severe congestive heart failure with a history of ischemic coronoary artery disease . . ."

1991

(1) $335,423 TITLE: "Center for AIDS Prevention Studies"
SUB-TITLE: "CORE—ETHICS"
ABSTRACT: "The AIDS epidemic raises urgent ethical dilemmas. The Ethics Core has assembled an interdisciplinary team to analyze and help resolve ethical issues regarding testing for HIV infection, preventive and clinical care for persons with HIV infection, and research on HIV infection. . . ."

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1992

(1) $377,971 TITLE: Same as above.

1993

(1) $348,380 TITLE: Same as above.

TOTAL: $1,126,318

NOTE: Various patented transgenic mice research models used to test AIDS drugs have been developed, some with NIH grant monies. One model, invented by Michael McCune, Ph.D. of Stanford University, used the immune systems of aborted babies transplanted into a nude strain of laboratory mouse whose litters then were transgenic.

Appendix J

Brigid L. M. Hogan, Ph.D.
Vanderbilt University, School of Medicine

1988

(1) $120,136 TITLE: Molecular genetic Analysis of the Small Eyes Mutation
ABSTRACT: "The basic concept underlying this application is that mammalian eye development is specified by a number of genes which can be identified and cloned. The specific aim of the project is to characterize a set of mutations affecting one of these genes, known as the Small eyes (Sey), located in the central region of mouse chromosome 2 close to the b-2-microglobulin . . . locus. . . . Information gained about the genetics of eye development in the mouse is likely to be applicable to normal and abnormal human eye development. . . . The basic mechanisms of embryonic eye induction are also likely to be highly conserved between mammalian species.

1989

(1) $210,856 TITLE: Developmental Regulation of Matrix-Modeling Genes
ABSTRACT: "The extracellular matrix is an essential component of animal form and as such undergoes extensive modeling during growth and embryonic development. Many of the genes for structural components of the extracellular matrix, and for specific degradative enzymes and their inhibitors, have been identified and cloned . . . The model system to be used is the induction of the Spare gene in mouse F9 teratocarcinoma cells. . . . These proposals will be carried out in the context of other studies on genes regulating embryonic development and the abnormal behavior of cancer cells within the environment of the extracellular matrix."

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(2) $113,525 TITLE: Growth Inhibitors: Differentiation and Cancer
SUB-TITLE: "Role of TGF-BETA" Regulated Genes in Embryonic Development
ABSTRACT: "The aim of this research is to investigate the role played by two TGF & related polypeptides, TGF (Beta 2) and Vg-r, in the growth and differentiation of the mouse embryo. . . . . Finally, a long time goal will be to study the in vivo function of the Vg-r gene during development. One strategy will be to misregulate Vg-r expression in transgenic mice. Another will be to block its expression by homologous recombination with a manipulated DNA sequence in embryonic stem (ES) cel followed by transmission of the defective (null) gene through the mouse germline.

(3) $113,525 TITLE: Growth Inhibitors-Differentiation and Cancer
SUB-TITLE: Core-Transgenic Mouse facility
ABSTRACT: "This core will provide a centralized service for producing the ransgenic mice initially required in Program Projects 3 and 7. Specifically, the core will undertake the following procdures: (1) microinjection of fertilized one-cell mouse eggs with specific DNA contructs prepared by Program Project investigators, (2) injection of ES cells in blastocysts, (3) return the eggs . . . to pseudopregnant foster mothers, (4) screen for transgenic offspring . . . (5) organize the mating an pedigree analysis of transgenic mice, and (6) assist in the dissection an analysis of tissues from transgenic mice and embryos. Such a facility is not available at present on the Vanderbilt campus. Therefore, in addition to providing an increasingly important research tool for members of the Program Project, it should also catalyze interaction with other members of the Medical School who may wish to establish the technique or collaborate on

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projects related to the expression and mode of action of factors regulating growth and differentiation in vivo.

1990

(1) $213,988 TITLE: Developmental Regulation of Matrix-Modeling Genes
ABSTRACT: See abstract above with same title for 1989.

(2) $123,869 TITLE: Growth Inhibitors, Differentiation and Cancer
SUB-TITLE: Role of TGF-BETA Regulated Genes in Embryonic Develpment
ABSTRACT: See abstract above with same title for 1989.

(3) $123,869 TITLE: Growth Inhibitors, Differentiation and Cancer
SUB-TITLE: Core-Transgenic Mouse Facility
ABSTRACT: See abstract above with same title for 1989.

(4) $130,024 TITLE: Molecular-Genetic Analysis of the Small Eyes Mutation
ABSTRACT: See abstract above with same title for 1988, 1989, 1990.

1991

(1) $209,848 TITLE: Developmental Regulation of Matrix-Modeling Genes
ABSTRACT: See abstract above with same title for 1989 and 1990.

(2) $126,486 TITLE: Growth Inhibitors, Differentiation and Cancer

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SUB-TITLE: Role of TGF-BETA Regulated Genes in Embryonic Develpment
ABSTRACT: See abstract above with same title for 1989 and 1990.

(3) $126,498 TITLE: Growth Inhibitors, Differentiation and Cancer
SUB-TITLE: Core-Trangenic Mouse Facility
ABSTRACT: See abstract above with same title for 1989 and 1990.

1992

(1) $213,241 TITLE: Developmental Regulation of Matrix-Modeling Genes
ABSTRACT: See abstract above with same title for 1989, 1990 and 1991.

(2) $192,664 TITLE: Role of BMP-r in Mammalian Development
ABSTRACT: "The aim of this proposal is to eludicate the role in mammalian development of the gene product known as Bone Morphongenetic Protein-4 (BMP-r) ..... Homologous recombination in interactions in embryonic stem. (E cells will be used to introduce null mutation into the BMP-4a gene on Chromosome 14 and the BMP-4b gene on the X chromosome. Chimeric mice will be produced by blastocyst injection and used to generate hemizygous, heterozygous and homozygrous mutant mice. These will be analyzed for defects in morphogenesis and pattern formation. A similar analysis will be made of transgenic mice in which BMP-4 is misexpressed in ectopic sites in the embryo and adult under the control of heterologous gene regulatory sequences. For studying the synthesis, secretion and

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localization of BMP-4 in vivo and in transfected cell lines in vivo, polyclonal antibodies will be prepared against both the variable and conserved regions of the protein. Finally, the effect of BMP-4 protein will be investigated on Xenopus and chick embryos in vivo. Together, these different approaches will throw light on the role of BMP-4 in morphogenesis and pattern formation in the embryo, and provide basic information relevant to congenital defects and teratogenesis in humans."

(3) $136,507 TITLE: Growth Inhibitors, Differentiation and Cancer
SUB-TITLE: Role of TGF-BETA Regulated Genes in Embryonic Develpment
ABSTRACT: See abstract above with same title for 1989, 1990 and 1991.

(4) $136,507 TITLE: Growth Inhibitors, Differentiation and Cancer
SUB-TITLE: Core-Trangenic Mouse Facility
ABSTRACT: See abstract above with same title for 1989, 1990 and 1992.

1993

(1) $218,806 TITLE: Developmental Regulation of Matrix-Modeling Genes
ABSTRACT: See abstracts above with same title for 1989, 1990, 1991, 1992.

(2) $193,162 TITLE: Role of BMP-4 in Mammalian Development
ABSTRACT: See Abstract above with same title for 1992.

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1994

(1) $198,218 TITLE: Role of BMP-4 in Mammalian Development
ABSTRACT: See abstracts above with same title for 1992 and 1993.

(2) $126,216 TITLE: Growth Inhibitors, Differentiation and Cancer
SUB-TITLE: Role of TGF-BETA Related Genes in Regulating Normal Embryonic Develpment
ABSTRACT: See abstracts above with same title for 1989, 1990, 1991 and 1992.

TOTAL: $3,127,945.

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Mark R. Hughes, M.D., Ph.D., Assistant Professor,
Molecular Genetics, Cell Biology and Medicine;
Director, Prenatal Genetics Center,
Baylor College of Medicine

1989

(1) $147,769 TITLE: "Receptor Mutants in Vitamin D Resistant Rickets of Bone"
ABSTRACT: "The proposed research focuses on the molecular mechanism of action of the sterol 1.25 dihydroxyvitamin D with major emphasis in understanding the function and structure of the i intracellular receptor protein for this hormone. Despite very low abundance of the cellular receptor protein. . . , human expression cDNA libraries have been used to clone the full coding resign of the protein . . . The natural gene for the human receptor has recently been isolated and the intron-exon junctions identified."

(2) $4,612 TITLE: Same as above.

1990

(1) $146,295 TITLE: Same as above.

(2) $4,004 TITLE: Same as above.

1991

(1) $146,147 TITLE: Same as above.

TOTAL: $448,827

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Fernando A. Guerra, M.D., M.P.H.,
Director, Department of Health,
San Antonio Metropolitan Health District

1993

(1) $527,984 TITLE: U.S. Clinical Trial of Acellular Pertussis Vaccine
ABSTRACT: "This clinical trial will compare three lots of acellular pertussis vaccine with each other. In addition, a fourth arm of the trial will utilize the current whole cell vaccine. All four arms of the trial will utilize a pertussis vaccine combined with diptheria and tetanus. The Contractor will recruit approximately 2000 subjects who will be randomly assigned to one of the four arms of the trial. Immunizations will be administered at two, four and six months. Reactions will be monitored by follow-up phone calls made at 24, 72 and 168 hours after each immunizations. The data will be analyzed in conjunction with other collaborators to determine the safety."

1994

(1) $0 TITLE: U.S. Clinical Trial of Acellular Pertussis Vaccine
ABSTRACT: See above abstract for 1993.

NOTE: See Attachment (to come.).

Appendix J

John J. Eppig, Ph.D.,
Senior Staff Scientist, The Jackson Laboratory,
Bar Harbor, Maine

1987

(1) $110,922 TITLE: Cancer Center Support (Core) Grant
SUB-TITLE: Electron Microscopy Services
ABSTRACT: No Abstract provided.

(2) $166,756 TITLE: Regulation of Mammalian Oocyte Development
ABSTRACT: "The long term objective of this research program is to identify specific molecules and pathways that govern mammalian oocyte development and resolve their mechanism of action . . . Oocytes from strain I/LnJ mice express a very marked retardation of oocyte maturation kinetics, a trait that will be exploited in the second part of this proposal to identify specific molecules that regulate phosphorylase kinase, an enzyme that induces matruation of frog oocytes. Therefore, experiments are proposed determine whether retarded maturation kinetics is the result of a deficiency in oocyte phosphorylase kinase or some other lesion that may, or may not, be related to the phosphorylase kinase deficiency. For example, it is proposed to assess whether retarded maturation kinetics is caused by phosphodiesterase deficiency or other lesions that could prolong cAMP-dependent maintenance of meiotic arrest."

(3) $241,217 TITLE: Ooyctye Culture Conditions That Promote Embryogenesis
ABSTRACT: "The overall goal of this research program is to determine how mammalian oogenesis is regulated so that a gamete competent of fertilization and development to live young is produced. The focus of the project is on the conditions for

oocyte development in promote the acquisition of a full developmental capacity. Oocytes that were grown in vitro and induced to undergo maturation were fertilized and underwent prepost-implantation development, but at a lower frequency that oocytes grown in vivo and matured in vitro. . . ."

1988

(1) $98,732 TITLE: Cancer Center Support (CORE) Grant
ABSTRACT: No Abstract Provided.

(2) $167,786 TITLE: Regulation of Mammalian Oocyte Development
ABSTRACT: See abstract above with same title for 1987.

(3) $300,485 TITLE: Oocyte Culture Conditions That Promote Embryogenesis
ABSTRACT: See abstract above with same title for 1987.

(4) $143,337 TITLE: Development of Mammalian Oocyte-Granulosa Cell Complex
ABSTRACT: "Early in mammalian ovarian follicular development, granulosa cells associate with both the oocyte and the basal lamina that circumscribes the follicle. Later, however, during the development of the antrum, the granulosa cells become divided into two major groups. . . . Although abundant information on the role of granulosa cells in oocyte development has emerged in the last decade, little is known of how the oocyte or basal lamina might participate in granulosa cell development. . . . Aggregation chimeras will be prepared from 8-cell embryos of two congenic lines expression — expressing different isozyme alleles of the glucose-6-phosphate isomerase-1 locus, and the expression of these alleles in mural and cumulus

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granulosa cells in female chimeras will be determined to ascertain whether these two cell types develop from one or more progenitor cells that initially contact primordial oocyte during primitive follical formation. To determine whether contact with basal lamina promotes development of mural granulosa cells, and whether the absence of such promotes development as cumulus granulosa cells, granulosa cell development will be assessed by 2-dimensional polyacrylamide gel electrophoresis of proteins sythesized by cells grown in contact with basal lamina or under conditions that prevent cell adhesion to substratum.

1989

(1) $108,635 TITLE: Cancer Center Support (Core) Grant
SUB-TITLE: Electron Microscopy Services
ABSTRACT: No Abstract Provided.

(2) $166,581 TITLE: Regulation of Mammalian Oocyte Development.
ABSTRACT: See abstract above with same title for 1987 and 1988.

(3) $268,346 TITLE: Oocyte Culture Conditions That Promote Embryogenesis
ABSTRACT: See abstract above with same title for 1987 and 1988.

(4) $150,742 TITLE: Development of mammalian Oocyte-Granulosa Cell Complex
ABSTRACT: See abstract above with same title for 1988.

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1990

(1) $110,992 TITLE: Cancer Center Support (Core) Grant
SUB-TITLE: Electron Microscopy Services
ABSTRACT: See abstracts above with same title for 1987, 1988 and 1989.

(2) $176,113 TITLE: Regulation of Mammalian Oocyte Development.
ABSTRACT: See abstracts above with same title for 1987, 1988 and 1989.

(3) $277,397 TITLE: Oocyte Culture Conditions That Promote Embryogenesis
ABSTRACT: See abstracts above with same title for 1987, 1988 and 1989.

(4) $148,745 TITLE: Development of Mammalian Oocyte Granulosa Cell Complex
ABSTRACT: See abstract above with same title for 1988, 1989.

1991

(1) $119,882 TITLE: Cancer Center Support (Core) Grant
SUB-TITLE: Electron Microscopy Services
ABSTRACT: "Subproject Abstract Not Available, Parent Abstract: "The Jackson Laboratory was founded in 1929 by Dr. Clarence Cook Little as a mammalian genetics center with a special focus on the problem of cancer, on the role of genes in both normal and abnormal development and differentiation, and on the development of the requisite genetic tools which could be put to practical use by others in examining these questions. It is the premise of The Jackson laboratory that the fundamental

mechanism that control normal and neoplastic growth, differentiation, and development, is essential to understand how cancers originate, develop and metastasize. The investigations pursued by members of the Scientific Staff are interdisciplinary in nature, as is illustrated by the number and diversity of internal and external collaborative projects carried out at the Laboratory. In addition to specific cancer-related research, the basic research carried out by the Jackson Laboratory investigators lays the esssential ground work for a better understanding of neoplasia. . . . The Jackson Laboratory as a whole has been designated by the National Cancer Institute (NCI) as a Laboratory Cancer Research Center and with this application seeks continuation of its Cancer Center Support (CORE) Grant. The request is for continuing support for the current components of the grant and for additional support for two new components. CORE support is requested for only 20.6% of the total cost of the Resources and Services involved."

(2) $172,101 TITLE: Regulation of Mammalian Oocyte Development.
ABSTRACT: See above abstract with same title for 1987, 1988, 1989, 1990.

(3) $439,717 TITLE: Oocyte Culture Conditions That Promote Embryogenesis
ABSTRACT: See above abstracts with same title for 1987, 1988, 1989 and 1990.

(4) $145,595 TITLE: Development of Mammalian Oocyte-Granulosa Cell Complex
ABSTRACT: See above abstracts with same title for 1988, 1989 and 1990.

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1992

(1) $142,761 TITLE: CORE-Cancer Center Support Grant
SUB-TITLE: Electron Microscopy Services
ABSTRACT: See above abstracts with same title for 1987, 1988, 1989, 1990, 1991.

(2) $174,044 TITLE: Regulation of Mammalian Oocyte Development
ABSTRACT: See above abstracts with same title for 1987, 1988, 1989, 1990, 1991, 1992.

(3) $266,057 TITLE: Oocyyte Conditions That Promote Embryogenesis
ABSTRACT: See above abstracts with same title for 1987, 1988, 1989, 1990, 1991.

(4) $144,230 TITLE: Development of Mammalian Oocyte Granulosa Cell Complex
ABSTRACT: See above abstracts with same title for 1988, 1989, 1990, 1991.

1993

(1) $180,705 TITLE: CORE-Cancer Center Support Grant
ABSTRACT: See above abstracts with same title for 1987, 1988, 1989, 1990, 1991 and 1992.

I verify under penalty of perjury that the foregoing is true and correct.

s/ Rosemarie Engel

Appendix J

Date: August 12, 1994
State of: Pennsylvania
County of: Westmoreland

Sworn to and before me this
13th day of August, 1994
s/ Joan C. Hall Notary Public
My commission expires: September 29, 1997

[Seal]
Notarial Seal
Joan C. Hall, Notary Public
Murrysville Boro, Westmoreland County
My Commission Expires Sept. 29, 1997
Member, Pennsylvania Association of Notaries

APPENDIX K — DECLARATION OF DARYL A. CHAMBERS

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Civil Action No.
PJM-94-1703

MARY DOE, et al.,

Plaintiffs

vs.

DONNA SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, et al.,

Defendants

DECLARATION OF DARYL A. CHAMBLEE

Daryl A. Chamblee hereby declares as follows:

1. I am the Acting Deputy Director for Science Policy and Technology Transfer of the National Institutes of Health ("NIH"). The NIH is an agency of the U. S. Public Health Service, Department of Health and Human Services. I am making this declaration in official capacity and the statements herein reflect information known to me personally which I gained in the performance of official duties.

2. Prior to the enactment of the NIH Revitalization Act, DHHS regulations prohibited Federal funding of human *in vitro* fertilization research proposals unless such proposal was

reviewed by an Ethical Advisory Board and the Board had rendered its advice as to its acceptability from an ethical standpoint. No such advisory board had been established by DHHS since 1980. The NIH Revitalization Act nullified this regulatory requirement. Since passage of the NIH Revitalization Act, NIH has received approximately 40 applications for human *in vitro* fertilization research and research involving the human embryo resulting from this process.

3. Beginning in the Fall of 1993 I served as Co-Chair, with Duane Alexander, M.D., Director of the National Institute of Child Health and Human Development, of a steering committee composed of several other full-time NIH employees which was created to assist with the planning of an initiative to seek broad based advice about the acceptability of various areas of research involving *in vitro* fertilization for Federal funding and to recommend guidelines to govern such research.

4. Specifically, the Steering Committee was charged with proposing the composition and structure of a panel to serve as a subcommittee of the Advisory Committee to the Director, NIH, an advisory committee chartered in accordance with the Federal Advisory Committee Act, which subcommittee would serve as an NIH Human Embryo Research Panel ("the Panel"). The Steering Committee was also responsible for proposing the scope, process and timetable for the Panel's.

5. The Panel was created in January 1994, to assist the Advisory Committee to the Director in addressing the moral and ethical issues raised by the use of *ex utero* human embryos in research and to recommend to the Advisory Committee guidelines to govern the review of research proposals in this area of science as well as to govern the conduct of such Federally

funded research. Attached as Exhibit No. 1 to this declaration is a copy of a fact sheet prepared by NIH staff which more fully describes the Panel and its charge.

6. The Panel has held five meetings between February and June 1994, all of which were open to the public and at which participation by interested individuals and organizations was actively encouraged. Notice of each meeting has been published in the Federal Register. The Panel will hold one additional meeting in late September after which its recommendations will be submitted to the members of the Director's Advisory Committee. After that meeting, the Panel will be dissolved.

7. The Panel was not created to perform any work that would be done by an advisory board created pursuant to section 101 of the NIH Revitalization Act, Pub. L. No. 103-93, which amended the PHS Act by adding section 492A, 42 U.S.C. § 289a-1. An advisory board established under that authority would be for the purpose of reviewing research proposals which have been recommended for funding by an NIH peer review panel and for which ethical issues have arisen. The work of the Panel is preliminary to any review of research proposals involving human embryo research in that its purpose is to recommend guidelines to be used in conducting review of such proposals and the conduct of research, if the proposal is funded.

8. In fact, no Ethics Advisory Board authorized by section 101 of the Revitalization Act has been created and to my knowledge none is contemplated being created at any time in the near future.

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I declare under penalty of perjury that the forgoing is true and correct.

8-31-94
Dated

s/ Daryl A. Chamblee
Daryl A. Chamblee

Appendix K

Exhibit 1

NIH HUMAN EMBRYO RESEARCH PANEL
Fact Sheet

Background. Until June 1993, Federal regulations governing research on human subjects (45 CFR 46) required research involving *in vitro* fertilization (IVF) to be reviewed by an Ethics Advisory Board (EAB). Because of the absence of an EAB since 1980, Federal funding of IVF protocols was not possible. With the enactment of the National Institutes of Health (NIH) Revitalization Act of 1993 (P.L. 103-43), the regulatory provision requiring EAB review of IVF proposals was nullified. As a result, IVF proposals, as well as research involving human embryos that result from IVF or other sources, may now be considered for Federal funding.

Research involving the *ex utero* human embryo has many potential scientific and therapeutic benefits. Among the most direct and immediate possible gains is in the treatment of infertility and the advancement of preimplantation diagnosis of genetic and chromosomal abnormalities. Other research focusing on the processes of fertilization and implantation could clarify the causes of infertility. Studies of normal and abnormal early embryonic development could enhance understanding of the causes of pregnancy loss, birth defects, and the mechanisms of uncontrolled cell growth that occur in cancer. Other research efforts could be applied to the development of novel contraceptives. In the longer term, research on embryonic stem cells could have therapeutic applications in a broad range of areas, including bone marrow transplantation, repair of damaged tissues, and treatment of degenerative diseases of the nervous and muscular systems.

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The NIH has received a number of applications for support of research involving the *ex utero* human embryo as well as research involving parthenogenesis (the initiation of development of an ovum without sperm). Before proceeding with the consideration of specific human embryo research proposals for funding, however, the NIH must address the profound moral and ethical issues raised by the use of human embryos in research and develop guidelines to govern the review and conduct of Federally-funded research. The Human Embryo Research Panel has been established to assist the NIH in addressing those issues and in developing guidelines. The Panel is a multidisciplinary group of special consultants to the Advisory Committee to the Director, NIH (ACD) with broad expertise in the fields of basic and clinical research, ethics, law, social science, public health, and public policy issues.

Panel Charge. Panel members are being asked to consider various areas of research involving the extracorporeal human embryo produced by *in vitro* fertilization, i.e., in the test tube, or parthenogenesis and to provide advice as to those areas they view to be acceptable for Federal funding, areas that warrant additional review, and areas that are unacceptable for Federal support. For those areas of research considered acceptable for Federal funding, Panel members are being asked to recommend specific guidelines for the review and conduct of this research. Issues related to human germ-line gene modification are not within the Panel's purview. Research involving the therapeutic transplantation of human fetal tissue and research involving *in utero* human embryos or fetuses are also not part of the Panel's mandate because guidelines are already in place to govern such research. Panel members will develop a report of their conclusions and recommendations by June 1994. The report will be presented to the ACD for review. The ACD, in turn, will provide policy advice to the NIH Director.

Appendix K

Panel Meeting Schedule. All meetings of the Panel are open to the public. During its first meeting, February 2-3, 1994, the Panel established the following schedule of future meetings:

- Monday, March 14, 1994
- Monday & Tuesday, April 11-12, 1994
- Tuesday & Wednesday, May 3-4, 1994
- Tuesday & Wednesday, June 21-22, 1994

The June 21-22 Panel meeting will be held at the Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland. Individuals who plan to attend the meeting are urged to contact the office listed below to confirm Panel meeting dates, sites, and other logistical details.

Public Comment Process. A critical part of the process of considering the issues involved in Federal funding of human embryo research is to gain an understanding of the diversity of beliefs and opinions held about the moral status of the human embryo and about Federal funding of research involving the human embryo. The NIH encourages interested individuals and organizations to share with the Panel their views and perspectives on this important topic. Individuals and organizations who wish to submit written comments of any length should forward these to:

Steven Muller, Ph.D.
Chair, NIH Human Embryo Research Panel
c/o National Institutes of Health
9000 Rockville Pike
Building #1, Room 218
Bethesda, Maryland 20892

Appendix K

To ensure that public comments are available to the Panel during its deliberations, written comments should be received in advance of the Panel's final meeting.

Each meeting of the Panel provides an opportunity for interested individuals and organizations to make brief oral presentations to the Panel. During the Panel meetings held thus far, public commentary was heard in two-hour sessions. To register to make an oral statement before the Panel, individuals and organizations should contact Ms. Peggy Schnoor at the NIH by telephoning 301-496-1454 or by sending a facsimile message to 301-402-0280 or 301-402-1759. Oral statements must not exceed five minutes in length, and a copy of the remarks should be forwarded to the above address one week in advance of the scheduled presentation date. Opportunities to present statements will be determined by the order in which requests are received.

Appendix K

[Billing Code 4140-01-F]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health (NIH)

Notice of Meeting of Panel/Request for Public Comment

The fifth, and probably final, meeting of the National Institutes of Health (NIH) Human Embryo Research Panel will be held June 21-22 from 9:00 a.m. to 5:00 p.m. each day at the Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland. The Panel is a group of special consultants to the Advisory Committee to the Director (ACD), NIH, established to recommend guidelines for Federal funding of research involving the *ex utero* human embryo resulting from *in vitro* fertilization or other sources. At the June meeting, the Panel will work toward the resolution of outstanding issues and review a draft report of its findings and conclusions.

Background. Research involving the *ex utero* human embryo has many potential scientific and therapeutic benefits. Among the most direct and immediate possible gains are the treatment of infertility and the advancement of preimplantation diagnosis of genetic and chromosomal abnormalities. Other research focusing on the processes of fertilization and implantation could clarify the causes of infertility. Studies of normal and abnormal early embryonic development could enhance understanding of the causes of pregnancy loss, birth defects, and the mechanisms of uncontrolled cell growth that occur in cancer. Other research efforts could be applied to the development of novel

contraceptives. In the longer term, research on embryonic stem cells could have therapeutic applications in a broad range of areas, including bone marrow transplantation, repair of damaged tissues, and treatment of degenerative diseases of the nervous and muscular systems.

The NIH has received a number of applications for support of research involving the *ex utero* human embryo as well as research involving parthenogenesis (the initiation of development of an ovum without sperm). Before proceeding with the consideration of specific human embryo research proposals for funding, the NIH must address the profound moral and ethical issues raised by the use of human embryos in research and develop guidelines to govern the review and conduct of Federally-funded research. The Human Embryo Research Panel was established to assist the NIH in this effort. The Panel's charge is to consider various areas of research involving the *ex utero* human embryo and provide advice as to those areas it views to be acceptable for Federal funding, areas that warrant additional review, and areas that are unacceptable for Federal support. For those areas of research considered acceptable for Federal funding, the Panel will recommend specific guidelines for the review and conduct of this research. Issues related to human germ-line gene modification are not within the Panel's purview. The Panel's final report will be presented to the ACD for review.

During part of its first and second meeting, the Panel reviewed the wide range of scientific and human health benefits that could result from governmental support of research involving the *ex utero* human embryo. At the third meeting, Panel deliberations focused on issues related to the moral status of the human embryo and acceptability of areas of *ex utero* human embryo research; ethically acceptable sources of human embryos and oocytes, including informed consent requirements, issues raised by

compensation of sperm/egg providers, and concerns regarding commercialization; and, appropriate mechanisms/levels of review of research proposals involving the *ex utero* human embryo. The fourth meeting of the Panel was devoted to the consideration of a preliminary draft of proposed guidelines.

Public Comment Process. The NIH continues to seek public comment on these and other issues raised by Federal funding of human embryo research and encourages interested individuals and organizations to share with the Panel their views and perspectives on these important matters. Those who wish to submit written comments of any length should forward these to Steven Muller, Ph.D., Chair, NIH Human Embryo Research Panel, c/o National Institutes of Health, 9000 Rockville Pike, Building #1, Room 218, Bethesda, Maryland 20892.

Each meeting of the Panel has also provided an opportunity for interested individuals and organizations to make brief oral presentations to the Panel. To register to make an oral statement before the Panel, individuals and organizations should contact Ms. Peggy Schnoor at the NIH by telephoning 301-496-1454 or by sending a facsimile message to 301-402-0280 or 301-402-1759. Oral statements must not exceed five minutes in length, and a copy of the remarks should be forwarded to the above address one week in advance of the scheduled presentation date. Opportunities to present statements are limited and will be determined by the order in which requests are received.

The NIH will endeavor to provide seating for all members of the public who wish to attend the meetings. To ensure that adequate seating is available for the public, individuals interested in attending the meeting are asked to notify the NIH by using the telephone or facsimile numbers listed above. Individuals who

require special accommodations are also asked to contact Ms. Schnoor at the above number. General questions about the Panel or future meetings should also be directed to Ms. Schnoor.

Dated: May 20 1994

[STAMP] /S/ RUTH L. KIRSCHSTEIN, MD.
Ruth L. Kirschstein, M.D.
Deputy Director, NIH

NIH; OD; OSPTT; DSPAD; SCarr; 5/13/94; 496-1454
Retyped NIH; OD; 5/20/94
Official file located in OMA files 31/B3-11

APPENDIX L — EXCERPTED TRANSCRIPT OF NIH MEETING OF DECEMBER 2, 1994

NATIONAL INSTITUTES OF HEALTH

69TH MEETING OF THE ADVISORY COMMITTEE TO THE DIRECTOR

Friday,

December 2, 1994

Conference Room 10, Building 31
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

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REPORT OF MEETINGS ON COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CRADAs)

Ms. Sandy Chamblee 201

Appendix L

* * *

[11] PROCEEDINGS (8:35 a.m.)

DR. VARMUS: We're going to continue our discussion of the Human Embryo Research Panel's report, and David Challoner has kindly agreed to moderate the discussion this morning.

DR. CHALLONER: Thank you very much, Harold.

We have on the phone Richard Corlin. Richard, can you hear me?

DR. CORLIN: Yes, I can.

DR. CHALLONER: Good. Well, we can hear you also. Are the waves washing up on Waikiki?

DR. CORLIN: It's rough, but somebody's got to do it.

(Laughter.)

DR. CHALLONER: Well, we welcome you, and we know how early in the morning it is out there. We appreciate your being here.

For those of you who have not had a chance to see USA Today, it was really quite stunning this morning to open up on page 2, in the premier advertisement location, "Donor Egg Immediate Availability. Over 100 Donors Available Now for Patients Requiring Donor Oocytes. No Waiting List. Suburban Washington, D.C." So if you think we're not right in the middle of

a major social upheaval, of which we are a part and of which the constituency on [12] both sides of this ad will have a lot to say, as well as other voices, I think that's quite real.

The format for this morning's hour, as I think we ought to try and organize it, is that I would like to open the floor to have about 10 or 15 minutes' further discussion by members of the advisory committee, the guests from the various councils, and the panel members who may still be present. At that point, I will then close the floor to further discussion, except for members of the Advisory Committee of the Director, at which time we'll become more parliamentary in process in order to debate and act on the report that is before us.

Then, following that action — because having heard many of the sort of private caucuses last night and everybody's had a chance, then, to go home and watch the Vikings beat the Bears and to dwell on some of the issues that we discussed yesterday, I have a sense that we will probably be able to move rather quickly on the first issue before the advisory committee — the second issue then becomes one of implementation, in which there were many ideas brought forward yesterday, and implementation can be general in terms of both education or the concept of incrementalism. Whatever that means I think needs further clarification this morning in order to be helpful to Harold.

[13] So with that introduction about process, let me, then, open the floor for further discussion by any of the members and guests.

DR. ZELLER: I'm Jan Zeller, and I'm a representative of the National Institute of Nursing Research. I took into consideration much of our discussion yesterday and put a great

deal of thought into it last night. I guess I would come down in favor of incrementalism as we consider this document.

I think perhaps the discussion might be to consider parthenogenesis as an acceptable study to pursue in that we will not be involved in discussion involving purposeful fertilization of eggs in studies involving parthenogenesis, and additionally I feel that it will be much more acceptable for people to accept the idea of using spare embryos for this type of research.

But I feel that perhaps before we embark on purposeful fertilization of eggs for research purposes, we should consider one of the suggestions that was made here at the table yesterday, that perhaps further moral discourse on this issue should be undertaken, including numerous ethicists and moralists who have submitted some well-articulated papers to us and who have published such articles in various public forums.

So that would be my recommendation at this [14] point. Although I'm not a voting member of the committee, those are my thoughts based on the discussion we've had here today and the documents presented to us at the committee.

Thank you.

DR. CHALLONER: Other comments? Yes?

DR. GUYTON: David Guyton, representing the National Advisory Eye Council. It occurred to me that one of the major problems that research based in this area has a chance to help is the problem of infertility, and the whole population of the United States is aware of that problem, obviously. My own wife had a major problem with that, so I know that firsthand. And if we don't

have an opportunity to witness the process of fertilization and actually use that process to study the problem of fertility, I think we're tying our hands.

DR. CHALLONER: Paul?

DR. MARKS: Yes. I am inclined to agree with David. I think that if we cannot justify this program on scientific and potential clinical applications, obviously the program shouldn't go forward. I think that if we can justify the program on the basis of its scientific excellence and its potential for valuable clinical advances in the various areas that have been dealt with in the report, any decision to go incrementally can't be, I think, [15] strongly supported by the scientific issues at stake here and becomes an issue more related to the ethical and political aspects of implementation.

I think we want to separate the two. There's no question that we have to be very sensitive to and be able to successfully address the ethical concerns and the political concerns, and clearly if we can't do that, we're not going to have a very good program overall. But I think approaching the science in an incremental fashion is really trying to deal with the ethical and political issues, and I, for one, feel that if we can use our ability to deal with the latter, which have to be dealt with head on and faced up to and everybody's viewpoint considered, hopefully we'll be able to come to some consensus that the value of this science is so great that it should go forward.

DR. CHALLONER: Thank you, Paul.

Gail?

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DR. CASSELL: As a scientist, I believe very strongly that the benefit to everyone from this research is so strong that, personally, I would say that it is unethical for me personally not to approve the report and the recommendation. I would say that I agree with Dr. Marks that the two issues should be separated and would like to see us consider that possibility and maybe even take a vote to approve the report and then deal with the [16] issue of the implementation and our other concerns.

DR. CHALLONER: Thank you, Gail.

Yes?

DR. BRACIALE: Tom Braciale, DRG. It seems to me that one of the essential issues here is one that the advertisement brought up.

DR. MARKS: I can't hear you.

DR. BRACIALE: Okay. One of the central issues and a point that perhaps could be stressed in this report or in an introduction to this report is the reality that this kind of in vitro research, in vitro manipulation of embryos, is now going on in the private sector. No matter what our personal feeling about this is, it's a reality. If NIH-sponsored research can make egg implantation more efficient and, therefore, decrease the number of fertilized ova that are destroyed during in vitro fertilization and are not used, or even decrease the cost of an IVF program, that may be justification enough for many individuals to support this.

I think that we can't argue this at the level of the science. Either this kind of approach is ethical and legal or it's unethical and illegal, and if it's the latter, the politicians have to deal with

the infertile couples to argue out whether this kind of technology is appropriate to be employed.

[17] DR. CHALLONER: Thank you.

Further comments or questions? Yes?

DR. KRULWICH: I can't help but add a somewhat different point of view again, to bring up a thought. Of the experience we've had in the last few years on animal research, I think we would say the same things, that as scientists — there's no question what we'd say — that we understand the benefits and the vast importance and, indeed, the ethical imperative of doing certain kinds of research as human beings.

Nonetheless, in the face of all sorts of outside and very real concerns and pressures and groups, we've modified the way we do business, and there are analyses of how to use the fewest and all that sort of stuff. We have to take the experience from this and other things and sort of apply it to an even more sensitive issue.

So, for example, while I still agree with what's been said, first of all, and would accept the report in total — I have no question about that — still, with respect to implementation, I think since its sensitivity and some aspects of incrementalism and assurance are probably very important politically — for example, I agree, if you want to do fertility research, which I think we do, you have to study fertilization. You could, [18] however, try very hard, or do an RFA to start with, to have the first limited studies being directed at finding a marker for oocyte maturation that would correlate very well with fertilizability and then attempt to use that marker for the study of how you get to that marker as opposed to making fertilization itself.

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I mean, there are a number of things one could think of and try. I do think the sensitivities are still very important and the politics are very sensitive.

DR. CHALLONER: Thank you, Terry.

Other comments?

(No response.)

DR. CHALLONER: Well, hearing none at this point, then, let me now ask that the floor just be available to the members of the advisory committee for purposes of action. As I suggested initially, and as I think Gail may have already commented, I think it may be effective or efficient for the remainder of our time — there, I believe, is a consensus in the committee to accept the report on behalf of the Advisory Committee of the Director from its subcommittee, with thanks and praise for a job extraordinarily, impressively well done, and I would entertain some motion to further discussion.

Gail?

DR. CASSELL: I would make a motion that this [19] committee accept the report that we have been presented.

DR. STEMMLER: I'll second that motion.

DR. CHALLONER: Moved and seconded. All right. Discussion on that motion?

DR. STEMMLER: Well, my personal inclination, if I may, Mr. Chairman, is to at least understand that we, as a committee,

cannot or probably should not second-guess the content of a report that was written and explored so thoughtfully and thoroughly, and that in its entirety, it becomes a very useful document setting forth an issue to the director or the National Institutes of Health.

I think that it's our responsibility to understand the value of the work that's been contributed, and I think it's important that we do accept this report and devote most of our time and discussion this morning into advising the director as to what to do with it now that he has it.

DR. CHALLONER: Thank you, Ed.

Further discussion from the committee?

(No response.)

DR. CHALLONER: Just to inform the committee, I have Nan Keohane's proxy this morning in this regard, and she will be voting favorably on this matter.

Any further discussion?

(No response.)

[20] DR. CHALLONER: If not, then, I will call the question, and I think so that the members' votes can be recorded, I will ask that you raise your hands, and I will call, Richard, for your input at the end of this.

All those committee members in favor of the motion, signify by raising your right hand.

(Show of hands.)

DR. CHALLONER: Have you got it, Ruth?

DR. KIRSCHSTEIN: I get six. Is that correct? Seven.

DR. CHALLONER: And Nan is eight, and me.

DR. KIRSCHSTEIN: Is that correct? Eight, and we haven't heard from Richard.

DR. CHALLONER: Richard?

DR. CORLIN: I'm in favor of it.

DR. CHALLONER: In favor. All right.

All those opposed, like sign.

(No response.)

DR. CHALLONER: Are there any abstentions?

(No response.)

DR. CHALLONER: I think we have everybody who's here. All right. Thank you very much. We have accepted the report.

Now onto the next part of the discussion that has already been alluded to, to help clarify as best we

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APPENDIX M— WHITE HOUSE PRESS RELEASE DATED DECEMBER 2, 1994

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release December 2, 1994

Statement by the President

The Director of the National Institutes of Health has received a recommendation regarding federal funding of research on human embryos. The subject raises profound ethical and moral questions as well as issues concerning the appropriate allocation of federal funds. I appreciate the work of the committees that have considered this complex issue and I understand that advances in in vitro fertilization research and other areas could derive from such work. However, I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research. In order to ensure that advice on complex bioethical issues that affect our society can continue to be developed, we are planning to move forward with the establishment of a National Bioethics Advisory Commission over the next year.

APPENDIX N — HHS LETTER TO SENATOR SANTORUM DATED APRIL 7, 1995 WITH ATTACHMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

The Honorable Rick Santorum
United States Senate
Washington, D.C. 20510-3804

Dear Senator Santorum:

I am writing in reply to your letter of March 10 regarding the "adoption" of a human embryo that results from an in vitro fertilization (IVF) procedure. You specifically requested that the National Institutes of Health (NIH) consider the expressed interest of your constituents, Michael and Susan Claudy, in such an adoption and to advise you about our position in this regard.

Before addressing your question, I would like to clarify the nature of the research currently under consideration by the NIH. On December 2, 1994, the President directed that the NIH not allocate resources to support "the creation of human embryos for research purposes." The directive means that the NIH may not support research that involves the fertilization of a human egg in vitro in which there is no intent to transfer the resulting embryo to establish a pregnancy. However, the directive does not apply to research that involves an embryo already fertilized for a treatment purpose that is subsequently donated by a couple for study in research.

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In the clinical practice of IVF, for medical reasons, more eggs are usually retrieved and fertilized than are transferred at one time. The untransferred embryos, which are sometimes called "spare" embryos, can be frozen for later use, donated to another couple for treatment purposes, donated for study in research, or discarded. Decisions as to the disposition of an untransferred embryo, if any, rest with the couple who generated the embryo.

At this juncture, the NIH is still reviewing the report of a panel that met last year to study the ethical, medical, scientific, and public policy implications of Federal funding of research involving human in vitro fertilization and the preimplantation embryo. The panel's report recommends that a number of stringent safeguards should be put in place to ensure the ethical conduct of such research. One of these safeguards is that informed consent of the couple generating the embryo must be obtained, and that in order for their decision to be fully informed, the specific nature and purpose of the research must be part of the information conveyed to the couple. I can assure you that if NIH decides to initiate funding of the research not affected by the President's directive, informed consent will be included as a requirement for the conduct of such research. This will ensure that an IVF embryo is not donated for a research purpose without the consent of the couple who generated the embryo. Such a couple would always have the option to donate an embryo to assist another couple in their efforts to have a child.

I have enclosed background materials on NIH's year-long effort to develop a responsible public policy for research involving human in vitro fertilization and the preimplantation embryo, in case you wish to provide additional information to Mr. and Mrs. Claudy about this issue.

Sincerely,

s/ Sandy Chamblee
Daryl A. (Sandy) Chamblee, J.D.
Acting Deputy Director for
Science Policy and Technology
Transfer

Enclosures

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ATTACHMENT 1

COUNTRIES WHICH PROHIBIT CREATION AND USE OF HUMAN EMBRYO FOR RESEARCH PURPOSES

The following nations of North America, Western Europe and Australia *prohibit* the creation of human embryos for research purposes. IVF fertilization is permitted *only* in connection with assisted procreation. Breach of the law is punishable by fine or prison sentence.

South Australia Prohibits human embryo research which 'may be detrimental to an embryo.'

Western Australia Human embryos may *only* be created by IVF for purposes of implantation into a particular women.

Denmark Draft Legislation requires the 'assumption that human life takes its starting point as from the time of conception' and provides for the protection of human embryos.

Germany The law on the Protection of Embryos . . . . makes it a criminal offence . . . to fertilize human ova for research and to do any destructive or damaging embryo research.

Mexico Assisted fertilization shall be permissible only if applied to resolution of sterility that cannot be resolved in any other manner.

Norway Prohibits research on fertilized eggs.

Spain IVF fertilization is permitted for the *sole* purpose of procreation. It is an offence to fertilize ova other than for procreation.

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Sweden IVF fertilization for purposes of procreation only.

Switzerland Prohibits 'trade in and the misuse of embryos for pharmaceutical purposes.'

United States Fifteen states prohibit or restrict non-therapeutic experiments on human fetuses and embryos. Some state prohibitions are backed by criminal sanctions. For example:

Illinois State Attorney has ruled that a physician would violate the law if he or she wilfully endangered or injured the conceptus in the pre-implantation stage through abuse or harmful experimentation.

Louisiana Prohibits creation of human embryos for research purposes.

Source: *Embryo Experimentation: Ethical, Legal and Social Issues,* Peter Singer, Helga Kuhse, Stephen Buckle, Karen Dawson, and Pascal Kasimha. Cambridge University Press, 1993.

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ATTACHMENT 2

THE 1993 McGIVNEY LECTURE SERIES:

JÉRÔME LEJEUNE

Professor of Fundamental Genetics, University of Paris

Jérôme Lejeune holds degrees in medicine from the University of Paris and in genetics from the Sorbonne Faculty of Science. Specializing in pediatric congenital diseases and, more particularly, mental retardation, he is the first researcher to identify the genetic cause of an inherited disorder, Down's syndrome. Dr. Lejeune was one of the expert witnesses at the 1989 "frozen embryo" trial in Tennessee and has been one of the foremost international defenders of the humanity of the child in the womb. His presentations will address the ethical implications of genetic research on some of the most important issues confronting society today.

HUMAN NATURE & SCIENTIFIC KNOWLEDGE

*

Tuesday, October 26
The Origin of Man

Wednesday, October 27
Physiology of Human Intelligence

Thursday, October 28
Natural Morality and Sexual Behavior

Appendix N

Friday, October 29
Biological Happening or a Future for Mankind?

*

7:00 P.M.
St. Catherine Auditorium, Providence Hospital
1150 Varnum Street, N.E., Washington, D.C.

Providence Hospital is conveniently located (off of Michigan Avenue) in the vicinity of The Catholic University of America. Plenty of free parking is available for those attending the lectures

Continuing Education Credits are available for those who attend the entire series.

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Appendix N

HUMAN NATURE & SCIENTIFIC KNOWLEDGE

BY JEROME LEJEUNE

Professor of Fundamental Genetics, University of Paris

1993 McGivney Lecture Series

(There follows a transcription of a video recording of a lecture by Professor Jerome Lejeune, played in open Court before the Honorable Peter J. Messitte on September 13, 1994.

The original lecture was delivered by Professor Lejeune at Providence Hospital the evenings of Tuesday, October 26 to Friday, October 29th, 1993, to the adult medical and academic community there assembled.)

Jerome Lejeune M.D., Ph.D. held a degree in medicine from the University of Paris and in Genetics from the Sorbonne Faculty of Science. He was professor of fundamental genetics at the Rene' Descartes University of Paris. Fellow of the Pontifical Academy of Science (Rome) and the American Academy of Arts and Sciences (U.S.), he received the Kennedy Award for his discovery of the chromosomal basis of Mongolism (Trisomy 21).

"As I tried to say previously, there is a confession that every scientist should make at the beginning of a talk about human genetics. That is, living matter does not exist. There is nothing like living matter. Matter cannot live at all. Matter cannot reproduce itself and matter cannot ever be reproduced. And to make that clear, let's look at a statue. A statue can be reproduced and between the original and the mold and then between the mold and the replica there would be a contiguity of matter, atom to

atom, but what will be reproduced is not the matter of the original because it can be reproduced in plaster, in plastic, in bronze, in anything. Then what will be reproduced is not the matter but it is a form which was imprinted by the sculptor and it is exactly similar in biology. What is transmitted from generation to generation is not the matter, because the size of the first body would have been enormous so that a million, billions of bodies could be taken out of it. But in the first place the reproduction of a living system is much more complicated that duplicating an inanimate effigy and reproduction in life is more similar to what is done now with a television camera in which a tape is modified by menial change of imitation of a band according to signals which have been transduced from the picture to a special system so that the band will now contain coded information that nobody can see but that a special machine could transfer again and transform in your screen and television as another picture. It is roughly that way that the living systems are transmitting their message from one generation to the next generation. Now it is exactly the same with life. Life is encoded in a very complex matter and manner that we have not to describe, point by point, but on a very long ribbon that we call the DNA which is very similar to the tape band we have in a tape recorder. But information is written there according a code so that you don't see, you cannot read it, but it has to be transferred by a special system, a kind of head of lecture, just like a minitiscope so that now it's transferred not any longer in DNA but it's transferred to RNA. RNA, it's a kind of negative copy and RNA is now transferred by another system into a protein which is the machine tool that the cell is using to manifest life. Now, when we see that we realize progressively that really life is a kind of symphony. The symphony is written on a ribbon but you have to have a special minitiphone, tape recorder, so that this can be decoded and you get the music out of the code of the DNA. And the music is life itself. Then, when we speak about living matter

we just make a mistake. Matter is not alive but matter can be animated and what animates matter is exactly the information which is written inside the DNA and the enormous amount of information which is inside the tape recorder. Because if there are no tape recorder the DNA means nothing. It has to be read so that the letter does not give life, spirit does.

What I would like to try to discuss with you is whether there is human nature being given by the information included in the DNA and the cell. Whether there is some, how do you call it, the user's manual and whether there is also instructions for maintenance. You know the user's manual is a decalogue and the instructions for maintenance are just the commandments of the church. Are they written really in the life? At least, can we find a connection between those instructions and the life. Well the first we can find that there is a curious philosophical fact that essence precedes existence. That is totally demonstrable in genetics because, if you remember what I said at the beginning that the information is in the DNA and must be translated inside the nucleus in RNA which should be translated now in protein when at the beginning before the translation is occurred if you were wise enough to read what is written in the whole DNA of this very peculiar egg which nine months later we will call Peter or Margaret for example, which is already Peter and already Margaret by its information, if we could read we would see its essence written in plain letter but not yet expressed. And during the few divisions it progressively would express this information so that existence will now follow from the essence. And no matter you twist the words you will find that the definition of life is just as simple as that, essence precedes existence. I don't know if it is philosophy because Geneticists are not impressed by philosophy because they don't know it. Maybe if they knew they would have some reluctance to say those blunt statements as I do. Never mind, the things are like that.

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Then to summarize the best epitome of life would be just to read the beginning of the Gospel according to St. John: "In the beginning there is a message, this message is in the life and this message is life. And if this message is a human message, this life is a human life." That's the most experimental consequence of molecular biology of today and it's very comforting for the science of today that it took us only nearly two thousand years just to find that at the beginning there was the logos.

It happens that I travel a lot, too much to be honest, but as far as I can, in many countries I try to visit two very important places. One is a university or the hospital and the other is a zoological garden. Both places are very instructive. In universities I always meet very learned people, asking themselves very gravely, whether their children when they are very young, are not some kind of animals. But in the zoo I have never seen a congress of chimpanzees asking themselves whether their children, when they will be grown up will not become university professors. That seems to be a very little observation but it means that something must be written which is different in the two natures, the one of the chimp and the one of the man. And the very learned colleagues who do not see that are, with due respect to their knowledge, thinking like chimpanzees. Now how could we convince them that the tiny thing, one milimeter and a half, which contains the whole human nature is really a member of our kin. To do that we have to use all the resources of genetics and embryology.

The biological happening I wanted to discuss with you this evening is a very remarkable fact that what we call animation is in fact an alienation of the matter. Suddenly, some matter do not behave like ordinary matter but is forced to behave as information tells to the matter what it should do. And then, in the true sense of the term, life is, so to speak, an alienation of the matter. It begins

on a very peculiar surrounding. If we look at the history of life, it seems that life has begun inside the waters, at least it is what is told in the Bible. It is also what is told in the books about evolution. But curiously, we begin also in a very curious medium. Now, in the bottom of the sea you can recognize easily that this is seaweed. But in fact, it is not seaweed, it is sheweed. That is the lining of the uterus with electronic microscope at the time that it is ripe to receive the first implantation and it is remarkable that to the human eye it looks like seaweed and nobody can make a mistake about the diagnosis.

The beginning of life is a very rapid phenomenon which I have just made a little drawing about it. That after the entry of the sperm inside the zona pallucida, which is a kind of plastic bag which is in fact the wall of the private life of the early embryo. As soon as the head has gone through the membrane, here we see, that's a mice as you can recognize by the long thing. The head of the sperm is now coming to the zona pallucida and with that he will drill a hole, and you see that there is a little hole and now it is going inside and half of the head is now inside the zona pallucida. What you should remark that there is already a change in the molecular structure of the surface which has suddenly changed at the moment the hole has been drilled for the first time and which now is totally changing at the moment the whole head will go inside. As soon as the head is inside the zona pallucida becomes absolutely nonperforable by another sperm. That the door is definitely closed and all the information necessary and. sufficient is now inside and no information will come in during the whole life of the new individual. Then conception is really what happens at the beginning of life. And here we touch a very simple and moving conjunction between science and common language. At the very beginning when the information carried by the sperm has made the entry inside the egg and the whole information

necessary and sufficient is now inside this little sphere of one milimeter and a half, we know that everything necessary is spelled out and it is remarkable that we use the same word to define an idea coming in our mind and a new individual coming to life. We speak about conception. We have a conceptus, a concept of an idea we conceive an idea, and when a baby is conceived we call him a conceptus. And that is not a poverty of the vocabulary but it is in fact an extremely precise definition of what is the beginning of life. It is because there is a moment at which the language of nature has been so miniaturized as I told you previously that now we do not make the difference between information and matter; between spirit and body. We use one word, conception, to define the start of both of them because they are tightly united at this very moment. With the progression of the complexity the new being has to manifest all the information it contains and because he is bound to become a very big system compared to one cell, it begins to divide feverishly. But you have to remember that after the sperm has got in and that the first cell begins to split in two it is still inside the plastic bag, inside the zona pallucida and all the beginning of the embryonic development is totally protected from mother activity. It is totally independent. That is the reason why in vitro fertilization is at all possible. Because in nature the egg is free in the liquid which is around here and the sperm are swimming in it for reaching that egg so that the egg being protected by its little shell, so to speak, is really independent of the mother for quite a while — for five days. Then it divides first into two cells, and what was the surprise of the old embryologist, and it is described in most of the book, yet not any longer now, I don't know why but it is still true, that one of the cells split in two and the other remains unsplit and at the very beginning there is a stage of three cell which was a great surprise because you are supposing you divide by two, then in four, then eight, and sixteen, but that is not true. It begins by

three. The interest is very great and I will come back to that in a moment. Then this one divide, and this one which was late would progressively build the envelopes and those that were early will build the body. Then we come to four, then each of them divide we come to eight, we come to sixteen and what happens then it's a compaction and the cell begin to hook to each other and the little mass inside the plastic bag becomes now smaller than the plastic bag so that there is water around and it has contracted. Let's show you a picture of that so that you have an impression of what it looks like because a drawing is easier to define. But here you have to remember that it is not natural because the plastic bag has been removed. Not many of you would not see that, so it's mice and the plastic bag has been removed so that you see the cells and suddenly they compact. Now the results of that compaction is that the cells which are inside get compressed by those who are outside. Now, let's come back where we were. When you have sixteen cell it's like having in a big sphere, sixteen marbles. How could you put them inside? It's very easy. You have to put three in the middle and thirteen around. That is seven on the equator and three on the top, three underneath and three in the middle. Now, the result is that the three which are in the middle would get compressed suddenly decide that they will work together and that they will build the body. Now the surrounding ones which will now expand that way will build the membranes and later they will build the placenta. Membrane and the placenta are just as important as the initiation of the embryo itself because it makes a kind of space capsule in which this tiny cosmonaut will begin its own life which could not live at all if he was not producing himself, his own capsule. So to speak, it's like an astronaut who would be building around himself the shuttle entirely. At the end of another division one of the cells shift its metabolis and it is producing a shaft, maybe that cell, which is digesting the shell and the whole thing goes out exactly as if it was already an

animal. The way it goes out is like an animal going out — it hatched. And the hatching happens at around the sixth day because a division occur quite every twenty-four hours. That's very important because if the hatching is too early then the individual would go out inside the tube, because the tube is what carries the egg from the ovary to the uterus. And if it was hooking on the tube it would be a great danger because the tube cannot expand enough as a uterus and the extrauterine pregnancy give rise to rupture, to bleeding and they must be operated. I'll come back in a moment to that particular question because Professor May brought to my attention very interesting publication and I think it is important to come back to that but not to complicate too much, let's continue.

We have started the divisions and then we look that a fourth division we have sixteen cell, three in the middle. Now, you have to realize that an experiment it is possible with an egg which has divided up to eight cell, or to sixteen cell to remove some cells and to put other cells coming from another embryo. That's easy with mice and it has been made and the result is extremely interesting. You take an embryo of mouse which is bound to be a black mouse. You take another one which is bound to be a white mouse because you know the progenetors and it's easy to say that this one is a pure black and this one is a pure white. Now you take part of the white and you put it inside the black one after removing the cells so that the number of cells remains the same. In most of the case it dies because it is rather complicated intervention but in many cases it survives and what comes out is a tiny little mouse, perfectly healthy but on the fur you will see a kind of chessboard of parts which are dark, parts which are white and you see that two lines of cells have combined to build the organism. Experimentalists are never happy with one experiment so they try to now take three different strains — one black, one white and one

khaki and in that case you get rare mice who have this chessboard with three different colors. While we have tried, when I say we it's not me but it's a specialist, they have tried to put four different lines and they never get a baby mouse with four different colors. The top number is three. You can put four, five different cell lines, only three are to be found in the mouse because at the beginning the mouse is telling itself at the three cell stage we are not a population of cells. We are bound to be a mouse. Now if you manipulate it they lose that information because you have removed some cells and you have put other cells, but when they compress themselves, they compact themselves, again you have three cells in the middle and you cannot have more than three line in the resulting mice. So those experiments have shown definitely that furs of individuality was a kind of trinary system. We need to have three cells talking to each other to decide I am one individual and you cannot use more than three cells to define one individual. Now, this very peculiar system allows us to understand what are the twins. Twins are just an error of calculation of the number of division so that you reach the time at which you should trigger compaction. Look what happens. At the fourth division we have sixteen cells, we get compaction, we have one baby. Now if this compaction does not occur here but you have another division, then you will have thirty-two cells and inside the sphere of thirty-two cells you will have in the middle three plus three and twenty-six around and you will have twins, identical twins. Now if you have another mistake and you continue to divide then you would go to triplets. That's very interesting because it tells us that there is a calculating machine in this tiny embryo which is counting the number of division — I have to divide one, two, three, four, THEN I compact. Sometimes the then does not occur immediately that it divide another time and you get twins. So there is an extraordinary property that even arithmetic is already acting during the first cell cleavage. There is a counter

somewhere. We don't know how it is and probably it is very simple. It must be exchange between cells and chemical message and that would be related with the necessity of having an odd number. Because if there is an odd number the egg cells cannot be equal. So you have a system to count the number of egg cells that you have got.

What is now the reason of this presentation is that we know now that twins are carrying the same nature and in fact a set of identical twins is two person sharing the same nature. That for us is not very complicated to understand but it is most curious that some people can really feel it. I remember it was in the Academy of Moral and Sociological science in Paris, Political Science in Paris, I was giving a talk about the early embryo and one of my colleagues came after the talk and he told me well I did not want to say that in public but you know he was an old professor of law, he was nearly eighty-five or ninety at that time, I don't remember exactly, and he told me I was a twin. My brother died a few times ago in an accident and we had had exactly the same career. He was a professor of law like I am. And he told me you have said that twins were one nature split in two persons. Now I must tell you doctor, that for my brother and I the question of the trinity was never to be discussed because we felt it was possible. I was very much impressed by this kind of confession. He was a very learned man and really you have to be identical twins to understand that the idea of one nature split in two persons can be felt. Most of us have been made one by one. Nature is very kind with us and she takes the trouble of not doing a series of us. We cannot feel those things but twins do. But we know the contrary and the little mice I was talking about with the chessboard is the contrary because in that case we have united two natures in one individual. And that is known also in man. It happens sometimes that at the moment of fecundation when there are probably an error in the splitting of

the egg so that the egg is split in two cells and one sperm comes in it, one sperm comes inside the other and then the individual which will come out is a compound of two different genetic makeup. This has to occur at the very beginning, at the conception because if it occurs later it will be prevented by the closing of the zona pallucida. But if it has occurred just at moment of conception you can have hermaphrodite that is an individual having the sexual appendage of Hermes as a male and of Aphrodite as female and they are abnormal indeed but if you look at their cells you will find that they are XX as a woman, XY as a male, compounded in one individual and those camerics hermaphrodites are really two natures united in one person. That's taken together tell us that the beginning of the individual, that THE BEGINNING OF OUR PERSONAL LIFE HAS TO ARISE AT THE MOMENT OF CONCEPTION AND AT THE LATEST TIME AT THE SPLITTING IN THREE CELLS. THEN WHEN PEOPLE ARE DISCUSSING WHEN DOES OCCUR THE INDIVIDUAL, WHEN DOES OCCUR THE UNITY AND THE UNICITY WE CAN ANSWER — WE KNOW, IT OCCURS AT CONCEPTION AND IF THERE ARE SOME MISTAKE MAYBE A FEW HOURS AFTER CONCEPTION BUT NO LATER THAN THAT.

Well let us suppose that we agree because science tells us that, what is a human being. A HUMAN BEING IS A MEMBER OF OUR SPECIES. And then, if we are science, WHAT IS A PERSON. IT IS A HUMAN BEING ALIVE and science has no other answer.

Appendix N

CERTIFICATION

I certify that the foregoing is a correct transcript from the 32-minute portion of the video recording of lecture of Dr. Jerome Lejeune played in open Court before the honorable Peter J. Messitte on September 13, 1994 in the matter of Mary Doe et. al. v. Donna Shalala et. al. PJM 94-1703.

s/ Angela Viar — 12/21/94
Angela Viar — Date

APPENDIX O — REPORT OF THE HUMAN EMBRYO RESEARCH PANEL DATED SEPTEMBER 1994

[Omitted here but submitted separately as Lodging Appendix.]